Proposed Decision Memo for Thermal Intradiscal Procedures (CAG-00387N)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes that the evidence is adequate to conclude that thermal intradiscal procedures do not improve health outcomes. Therefore, CMS has determined that thermal intradiscal procedures are not reasonable and necessary for the treatment of low back pain and we propose to issue a national noncoverage determination for TIPs.

We are requesting public comments on this proposed determination pursuant to section 1862(l) of the Social Security Act. We are particularly interested in comments that include evidence we did not review or that assess how we evaluated the evidence included. After considering the public comments and any additional evidence we will make a final determination and issue a final decision memorandum.

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Proposed Decision Memo

TO: Administrative File: (CAG-#00387N)
Thermal Intradiscal Procedures

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SUBJECT: Proposed Coverage Decision Memorandum for Thermal Intradiscal Procedures (TIPs)

DATE: July 15, 2008

I. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes that the evidence is adequate to conclude that thermal intradiscal procedures do not improve health outcomes. Therefore, CMS has determined that thermal intradiscal procedures are not reasonable and necessary for the treatment of low back pain and we propose to issue a national noncoverage determination for TIPs.

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II. Background

Chronic pain is the most universal form of human stress and millions of Americans suffer from pain-related problems (Salovey, Seiber et al. 1992). Low back pain is a common condition with sixty to eighty percent of U.S. adults afflicted at some time during their life (U.S. Preventive Services Task Force 1996).

Low back pain can be defined as symptoms of pain, muscle tension, or stiffness localized below the costal margin and above the inferior gluteal folds, with or without leg pain (Manek, MacGregor 2005). Low back pain can be thought of as being either nonspecific or specific. In specific types of low back pain, the symptoms are caused by pathological conditions such as spinal fractures, cancer, or infection and can be identified and treated appropriately (Manek, MacGregor 2005). Approximately 90% of low back pain is of the nonspecific type (Manek, MacGregor 2005). In nonspecific low back pain, most patients' symptoms resolve satisfactorily within a relatively short time span. In the 5 – 10% of patients whose pain does not satisfactorily resolve, the symptoms can be disabling. Some psychosocial risk factors for the progression to chronicity have been identified (Manek, MacGregor 2005). Weiner reported documentation of nonspecific low back pain in Medicare beneficiaries growing in epidemic proportions. It is unclear if this is a true increase in low back pain prevalence (Weiner, Kim et al. 2006).

In general, the social and economic impact of chronic pain is enormous (Salovey, Seiber et al. 1992). However, in 2008, Martin reported, "Despite rapidly increasing medical expenditures from 1997 to 2005, there was no improvement over this period in self-assessed health status, functional disability, work limitations, or social functioning among respondents with spine problems" (Martin, Deyo et al. 2008). The growing list of treatment approaches offered as solutions for chronic low back pain (CLBP) has created confusion and frustration for the patients as well as clinicians and the third party payors responsible for providing access to care (Haldeman, Dagenais 2008a).

Identifying the cause for nonspecific low back symptoms remains challenging. Haldeman stated, "…we do not know the origin of low back pain in the majority of cases…" and attributes this conundrum to the unique anatomic complexity of the spine (Haldeman 1999). Weiner reported causative underlying pathology difficult to determine because low back pain, a complex clinical syndrome, derives from a multitude of causes, such as mechanical and nonmechanical factors and visceral disease (Weiner, Kim et al. 2006). Neurophysiologic mechanisms of pain sensation are poorly understood, adding to the difficulty in localizing the pain source (Haldeman 1999). Nachemson related the complexity of back pain not only to local pathology but also to biochemistry, pain physiology, brain science, psychology, sociology and economics (Schoene 2006).

Frequently, persistent low back pain is attributed to a damaged intervertebral disc, which bears some of the highest loads in the human body and is almost avascular (Huang, Sandhu 2004). Disc damage, or degeneration, can occur as an ongoing process where ultimately the disc's reparative capacity is overwhelmed, leading to continued changes. Huang and Sandhu stated, "it is not surprising that DDD [degenerative disc disease] is a common phenomenon in middle age and a universal condition in old age." While from a simple mechanical aspect it could be hypothesized that DDD is a cause for pain, disc degeneration is also observed in individuals without pain (Boden, Davis et al. 1990). While many have focused on the disc as the cause of pain, Nachemson felt its role in back pain causation was no more proven than those of other structures (Schoene 2006).

CLBP is a condition that is treated across many medical/surgical specialties. The education, training skills and experience of this diverse group have an influence on the individual practitioner's viewpoint on the management of CLBP (Haldeman, Dagenais 2008b). The development of reliable, high quality evidence to support the different treatment modalities faces its own set of challenges. The explosion of orthopedic technology has exponentially increased the understanding of the mechanics, biology and natural history of the spine (Shah, Albert et al. 2005). However, validation of new technologies is crucial to establish both safety and efficacy (Shah, Albert et al. 2005). Weinstein counseled, "Despite the meaning of the phrase, 'technological advances' are not always improvements. …It is true that new treatments can allow for improved care, but we should not assume they automatically do" (Weinstein 2007).

In 2004, Deyo offered, "The history of treatments for back and neck pain is generally one of small increments in benefit." He went on to say that it is hard to prove that most treatments provide greater improvements than the nonspecific effects of natural history, placebo and regression to the mean for both acute and chronic pain. Deyo further stated, "The literature is replete with conflicting results, modest effects, and weak studies." Deyo noted the scarcity of large trials in musculoskeletal diseases that are commonplace in cardiovascular disease and oncology (Deyo 2004). Haldeman stated, "…the question that needs to be answered is whether any treatment should be offered and widely used before there being sufficient research evidence to establish its efficacy, safety, and cost effectiveness" (Haldeman, Dagenais 2008b). In relation to treatment options for CLBP, Haldeman's assessment was, "...we are still in the era of caveat emptor (buyer beware)" (Haldeman, Dagenais 2008b). New technologies continue to be brought into practice with poorly designed studies that provide a false sense of security to practicing physicians about patient outcomes (Weinstein 2007).

Although discography is thought by some to be important in diagnosing discogenic back pain, "…controversy remains as to the accuracy and specificity of discography because of the inability to understand the mechanism which produces pain" (Peng, Wu et al. 2005). Provocative discography, described in the 1940's as a method of imaging discs by injecting contrast into the nucleus pulposus, has been controversial from its earliest use (Carragee 2000). In 2002, Jarvik and Deyo characterized the diagnosis of internal disc disruption (IDD) by provocative discography as controversial. In addition, the clinical importance of identifying high-intensity zones (HIZ), describing the presence of focal high signal in the posterior annulus fibrosus seen on imaging, which presumably represent annular tears, remains controversial (Jarvik, Deyo 2002).

The initial treatment of pain believed to be caused from degenerative disc disease is conservative care. Conservative care can include physical therapy, manipulation, massage, pain medications, and exercise. The majority of patients will have acceptable results with a non-surgical approach. When patients fail conservative care, surgery becomes an option. Until recently in the United States, surgical options available for degenerative disc disease have ranged from discectomies (open or microsurgical) to percutaneous nucleotomies, chemical and thermal nucleolysis and/or spinal fusion (Gibson, Wassell 2005). The last two decades have provided rapid technological advancements which have made minimal access spine surgery possible (Thongtrangan, Le et al. 2004).

Enhancement of patient outcomes by facilitating a quicker return to daily activities, diminishing pain and complications, and decreasing overall healthcare costs has motivated changes in spine surgeries over the years (Samartzis, Shen et al. 2007). Minimal access or minimally invasive spine surgery began to develop with the improvements in instrumentation and imaging (Samartzis, Shen et al. 2007). Derby stated, "The rationale for heating intervertebral discs was strongly influenced by animal and clinical investigations testing the ability of heat to stabilize joints by modifying collagen" (Derby, Baker et al. 2008).

The evolution of thermal intradiscal procedures involved the use of electrical and radiofrequency energy to apply or create heat within the disc to treat discogenic pain. Percutaneous thermocoagulation intradiscal techniques involve the insertion and heating of a catheter/probe(s) in the disc under fluoroscopic guidance (Urrutia, Kovacs et al. 2007). Derby stated, "The goals of thermal disc treatments are to remove unwanted tissue such as herniated discs, create a seal to limit expression of matrix components, shrink collagen tissue, and destroy nociceptors[1]. Although intradiscal heating can be accomplished through a variety of means, including electrocautery, thermal cautery, laser, and radiofrequency energy (RFE); most current intradiscal thermal treatments are performed using RFE" (Derby, Baker et al. 2008).

A review of the current literature reveals that the mechanism of the disorder, nonspecific CLBP, as well as the mechanism of action of the thermal intradiscal procedures remain uncertain. Derby reported that despite numerous in vivo and in vitro studies using human and animal models, the precise relieving mechanism of intradiscal heating is unclear. He went on to state that the theoretical explanations of mechanism of action are changes in disc biomechanics, annular contraction, thermally induced healing response, sealing of annular tears, annular denervation and/or decreased intradiscal pressure (Derby, Baker et al. 2008). Finch stated that attempts at applying the principals of pain reduction through thermal destruction of afferent nociceptive fibers to the lumbar intervertebral disc have not proven easy, due to the complexity of the afferent nociceptive pathways which, to date, are only partially understood (Finch 2004).

Derby summarized, “RFE may be applied with unipolar or bipolar probes. Similar to electrocautery, with unipolar RFE, currents pass through the probe to the body and to a grounding pad. The bipolar probe allows energy to pass through positive and negative poles on the probe, theoretically decreasing collateral damage. The bipolar devices may allow for greater control and focus of heat energy. A modification of the bipolar probe has been termed “coblation,” which has been claimed to generate plasma of high-energy inonized particles in the tissues surrounding the probe rather than a traditional heat lesion. The plasma can disrupt organic bonds, thus allowing debridement and effective heat treatment of soft tissues” (Derby, Baker et al. 2008). TIPs are proposed as an alternative to spinal fusion.

Direct radiofrequency (RF) lesioning of a disc was first performed in 1988 by Sluijter. This involved inserting a RF electrode into the central disc nucleus similar to provocative discography. With the tip of the electrode reaching temperatures of 70° C for several minutes, a lesion was created (Finch 2004). Subsequently, multiple lesions were created in the vicinity of the posterolateral annulus. A flexible RF catheter was subsequently introduced. This catheter is steered into position in the outer annulus from the contralateral side to the annular tear. The subsequent application of RF energy raises the temperature to 65° C in incremental steps over ten minutes. The spread of thermal energy was measured by placement of a thermocouple placed adjacent to the annular tear (Finch 2004).

The scope of this national coverage analysis (NCA) is TIPs which involve percutaneous intradiscal techniques utilizing devices that employ the use of an energy source, usually RFE, to apply or create heat within the disc for coagulation and/or decompression of disc material to treat symptomatic patients with annular disruption of contained herniated disc, to seal annular tears or fissures, or destroy nociceptors for the purpose of relieving pain. This includes techniques that use single or multiple probes/catheters, which utilize a resistance coil or other thermal intradiscal technology, are flexible or rigid, and are placed within the nucleus, the nuclear-annular junction or the annulus. TIPs are commonly identified as intradiscal electrothermal therapy (IDET), intradiscal thermal annuloplasty (IDTA), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), radiofrequency annuloplasty (RA), intradiscal biacuplasty (IDB), percutaneous (or plasma) disc decompression (PDD) or targeted disc decompression (TDD). At times, TIPs are identified or labeled based on the name of the catheter/probe(s) that is used (e.g. SpineCath, discTRODE, Accutherm, or TransDiscal electrodes). Each technique or device has its own protocol for application of the therapy. Disc decompression or nucleoplasty procedures that involve the physical removal of disc tissue without the use of a thermal energy source (such as the disc decompressor procedure) as opposed to the vaporization of disc tissue, are not within the scope of this NCA.

In December of 2006, CMS received a letter from the North American Spine Society (NASS) providing comment on the notice of the Final Rule for 2007 Medicare Physician Payment Schedule which addressed IDET (published in December 2006 Federal Register). NASS stated, “It is our belief that IDET is the subject of significant controversy among experts and that the scientific evidence demonstrating efficacy for IDET is inconsistent. At best, there is a small subset of younger, highly selected patients who obtain temporary benefit. At worst the procedure is no better than placebo. In addition, there have not been studies done demonstrating efficacy in patients over the age of 60.” The Society concluded, “At this time, the available scientific literature evaluating the clinical efficacy of IDET is conflicting. NASS does not believe this procedure has been well studied or its efficacy established in the Medicare population. If performed, NASS strongly recommends strict adherence to the selection criteria utilized in the Pauza study. Even in the best clinical practice, when these criteria are rigidly applied, only a relatively small number of patients obtain near complete relief. Because many people experience low back pain, the procedure could become quite costly without a demonstrated improvement in health benefit if it is applied indiscriminately and for improper indications.”

In that letter and in subsequent communications, NASS suggested that CMS review the literature on IDET to determine if IDET should be reimbursed. After a preliminary review of the literature, CMS identified numerous techniques operating on essentially the same premise and for essentially the same indications and decided to open a national coverage analysis on TIPs. CMS recognizes that there are some differences among the techniques and devices employed in TIPs; however, we believe the various techniques utilized for TIPs use the same function and seek the same desired outcome (the application or creation of heat within the disc to relieve pain) and should be grouped under one NCA.

III. History of Medicare Coverage

Medicare does not currently have a national coverage determination (NCD) on TIPs. Decisions on coverage for TIPs have been made by the local contractors. A search of the local coverage decisions (LCDs) database for thermal intradiscal and intradiscal electrothermal therapy identified thirteen LCDs from the local Medicare contractors. Nine policies stated non coverage for Nucleoplasty and IDET (annuloplasty) or other similar minimally-invasive ablative procedures – using radiofrequency, laser or direct heat energy source - and their associated services because these services are not proven to be effective and are considered to be not reasonable and necessary. Four LCDs stated that regardless of the technique, coagulation and decompression of disc material by electrothermal or radiofrequency techniques were considered investigational. However, these four LCDs allowed individual consideration for IDET for patients meeting strictly defined criteria.

Benefit Category

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. §1812 (Scope of Part A); §1832 (Scope of Part B); §1861 (Definitions of Services, Institutions, Etc.). TIPs would be eligible for coverage under Part B, as physician services, under §1861(q), hospital services incident to physicians' services rendered to outpatients under 1861(s)(2)(B) and ambulatory surgical centers under 1832(a)(2)(F)(i). This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

IV. Timeline of Recent Activities

January 15, 2008	CMS initiates opening a NCD for TIPs. Initial 30-day public comment period begins.

February 13, 2008	Meeting with Smith & Nephew and other interested parties on IDET.
February 14, 2008	Initial 30-day public comment period closes.
April 3, 2008	Meeting with Baylis Medical on Biacuplasty.
July 15, 2008	Proposed Decision Memorandum posted and 30 day public comment period begins.

V. Food and Drug Administration (FDA) Status

There are numerous catheters that have received 510(K) clearance from the FDA for use in thermal procedures. Some catheters have a specific indication for use in the intervertebral disc and many are indicated for the creation of heat lesions for the relief of pain. Some of the catheters identified for use in the intervertebral disc are identified below. This is not intended to be a complete list of all the catheters that may be used in thermal intradiscal procedures. A point of interest is that all the catheters listed below received 510(K) clearance because they were determined to be substantially equivalent to a predicate device and those predicate devices were determined to be substantially equivalent to another predicate device and so on. It should be noted that TIPs are the topic of this NCA; not specific catheters used in the application of heat within the intervertebral disc.

The IDET technique is commonly identified with the use of the SpineCath Intradiscal catheter. Original 510(K) clearance was obtained by Oratec. In 2002 Oratec was acquired by Smith & Nephew. In 1998 Oratec obtained 510(K) clearance from the FDA for the SpineCATH Intradiscal Catheter (K974464) (substantially equivalent to Oratec EndoTAC Monopolar Cautery Probe K972358). The identified indication for use was for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated disc. The catheter was for use only with the Oratec generator. (Link to FDA web page:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&id=K974464)

Subsequently, in 1999 Oratec obtained 510(K) clearance from the FDA for the SpineCATH intradiscal catheter Model 9200 (K993967) (predicate device – SpineCATH Intradiscal Catheter K974464). The intended use was for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. The catheter was intended for use with Oratec ElectroThermal Spine System Generator. (Link to FDA web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&id=K993967)

In October of 2000, Radionics obtained 510(K) clearance for the Radionics RF Disc Catheter Electrode System (K001741) (predicate devices - Oratec SpineCATH Intradiscal Catheter K974464 and Radionics RFG-3CPlus RF Lesion Generator K982489). This catheter seems to be associated with the PIRFT technique. The indication for use of this system, in combination with the Radionics RFG-3CPlus RF lesion generator, was for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. (Link to FDA web page:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&ID=K001741)

In January of 2002, Oratec Interventions, Inc., received 510(K) clearance from FDA for the Nucleotomy Intradiscal Catheter (K013622) (predicate device - SpineCATH Intradiscal Catheter K993967). The intended use was for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. (Link to FDA web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=6341)

In September of 2003, Baylis Medical Transdiscal system received 510(K) clearance from the FDA (K031951) (predicate device not identified on FDA website). The intended use was for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. (Link to the FDA web page:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=12189)

In January of 2007, the Baylis Medical TransDiscal system received 510(K) clearance from the FDA (K062937) (predicate devices – Baylis TransDiscal System K031951 and the Baylis Pain Management Cooled Probe K053082). (This catheter seems to be associated with the Biacuplasty technique.) The intended use was the creation of RF lesions in nervous tissue including that which is situated in intervertebral disc material. The two TransDiscal probes and the Pain Management Pump unit, connected to the Baylis Pain Management Generator, deliver the RF energy. (Link to FDA web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=22934)

In February of 2008, Smith & Nephew, Inc., received 510(K) clearance from the FDA for the Smith & Nephew Intradiscal Catheter System (K073466) (predicate devices – Nucleotomy Catheter K013622 and the Spinecath Intradiscal Catheter K993967). This system consisted of the Spinecath Intradiscal Catheter and the Acutherm Decompression Catheter and was used as part of the IDET and TDD techniques. The intended use of the Spinecath Intradiscal Catheter is identified above. The intended use of the Acutherm Decompression Catheter was for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. (Link to FDA web page:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=26487)

VI. General Methodological Principles

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix A. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

Public comment sometimes cites the published clinical evidence and gives CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

Assessment of outcome in the treatment of chronic low back pain

The evidence CMS examined had as its focus health outcomes, meaning the benefits and harms of a particular treatment. Outcomes that are usually heavily weighted by CMS - morbidity and mortality - are difficult to examine in the context of treatment for CLBP because pain is a symptom, not a disease. Sustained improvement in pain perception and a reduction in the pain-related functional restriction are generally the focus of study outcomes as opposed to managing a disease such as diabetes where measures such as progression to renal failure, blindness, and death are used. Measuring a reliable improvement in chronic pain attributable to a treatment is problematic as pain is particularly responsive to the placebo effect. Additionally, measuring the course of back pain is difficult as the natural history of this symptom is understood to be extremely variable (von Korff 1994). Therefore, clinical trials with appropriate controls utilizing independently assessed validated instruments are most heavily weighted. The measurement of treatment effect for low back pain has shifted from physician-based assessment (with outcomes of excellent, good, fair, and poor) to a patient-based self-report of pain and disability (Hagg, Fritzell et al. 2003).

Measurement of the effects of treatment for chronic low back pain should reflect the complex, multifaceted nature of the disorder (Bombardier 2000; Deyo, Battie et al. 1998). Groups have advocated for inclusion of standardized measures in five areas including function, symptoms, general health status, work disability, and satisfaction with care (Deyo, Battie et al. 1998; Bombadier 2000b). Standardizing the measures facilitates study comparison. The most commonly used measures of back specific function include the Roland-Morris Disability Questionnaire (RDQ) and the Oswestry Disability Index (ODI). The Low Back Outcome Score (LBOS) is a lesser used measure. These measures are an indication of the extent to which a person's functional level is restricted by pain. General health status can be measured with the SF-36, which has the advantage of norm-based scoring on diverse populations and has been validated for back pain (Bombadier 2000b). Pain intensity can be measured with the bodily pain subscale of the SF-36 (Bombadier 2000b) or the visual analog pain scale (VAS) (Deyo, Battie et al. 1998). While patient satisfaction is important, its measurement is more ambiguous. No single measure is preferred, however various approaches have been suggested (Bombadier 2000b). CMS weights those studies with reliable, validated outcomes most heavily.

With the use of any of these instruments for measurement, a consideration must be given to the clinical meaning of a change in the score (or, for a change in instrument score to be clinically meaningful the patient should experience a change in how he feels or functions). Other considerations include the error of measurement of the instrument used and the clinical importance of a statistically significant score change. In a 2003 study by Hagg of 289 patients treated surgically or non-surgically in a randomized controlled trial, the standard error of measurement of the ODI was four units, with a 95% tolerance interval of 10, and the minimum difference that appeared clinically important was 10 units (Hagg, Fritzell et al. 2003). The minimal clinically important difference of VAS back pain was 18-19 units [on a 100 point scale] with a 95% tolerance interval of 15 (Hagg, Fritzell et al. 2003). These recommendations are similar to those by Ostelo who also noted that when baseline was taken into account a 30% improvement should be the guide for the minimal important change (MIC) (Ostelo, Deyo et al. 2008).

The SF-36 Health Survey can be used to measure general well-being. Since the SF-36 is not specific to any disease, the disease burden of specific conditions can be compared (Ware 2003b). Of the eight health profiles (36 questions total) that are included in this survey, each can be reported independently, such as bodily pain, or as a composite of subscales such as the mental health component. Norm based data for large diverse populations are available for comparison. For instance, for the general U.S. population the bodily pain mean score is 75.5 (+/-23.6).

In some studies of low back pain treatments, physiologic measures such as segmental mobility (as measured by range of motion) were reported; however, the correlation with clinical outcomes remains unclear. For TIPs, no physiologic outcomes have been reported.

Well-designed clinical trials can provide the strongest evidence for treatment effect. Well constructed randomization protects against bias and inclusion of an appropriate comparator facilitates study interpretation. In pain treatment trials, the natural history of the disease, regression toward the mean and the placebo response are important considerations. For these reasons, an appropriate comparator is necessary for accurate interpretation. Accurate interpretation of pain treatment trials also necessitates reporting of concomitant pain treatments, most importantly analgesic use. In the case of research in the area of pain treatment, more weight will normally be accorded to studies that are designed to guard against the placebo response and where the natural history of the disease and regression toward the mean are accounted for.

Adverse events are important medical outcomes. Patients need this information to make well-informed choices. For instance, for TIPs (including discography), studies that report all infectious, neural, allergic hypersensitivity and vascular complications as well as probe fractures and muscular spasm are desirable. Studies that provide an inclusive examination and explanation of adverse medical events are generally given more weight.

B. Discussion of evidence

1. Question:

The development of an assessment in support of Medicare coverage decisions is based on the same general question for almost all requests: "Is the evidence sufficient to conclude that the application of the item or service under study will improve health outcomes for Medicare patients?" For this NCD, the question of interest is:

Is the evidence sufficient to conclude that TIPs will improve health outcomes in the Medicare population with low back pain?

2. External technology assessment (TA)

CMS did not commission an external TA for this NCA; however, a number of external technology assessments were identified in the literature.

California Technology Assessment Forum (CTAF)
October 2003

CTAF conducted a technology review in 2003 of intradiscal electrothermal therapy. The recommendations were that intradiscal thermal therapy with the Radionics RF system and with the Oratec IDET system did not meet CTAF TA criteria.*

* These criteria were not met:
The improvement must be attainable outside the investigational setting.
The technology must be as beneficial as any established alternatives. The technology must improve the net health outcomes.

National Institute for Clinical Excellence (NICE)
August 2004 and May 2006

In guidance documents, NICE concluded that the evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy (2004), percutaneous disc decompression using coblation (2006), and radiofrequency thermocoagulation (2004) for lower back pain was not adequate to support the use of this procedure without special arrangements for consent and for audit or research.

Institute for Clinical Systems Improvement (ICSI)
April 2002

The ICSI technology assessment committee found:
1. There was no convincing evidence that shows the short or long-term clinical efficacy of this procedure.
2. Short term studies have indicated few adverse effects of IDET, but information on long-term effects was limited.
3. The long-term effects of thermal coagulation of the disk were unknown at that time.

Danish Centre for Evaluation and Health Technology Assessment
December 2003

The Danish centre for evaluation and health technology assessment came to this conclusion on the clinical effect of intradiscal electrothermal therapy for low back pain: “As there was no convincing documentation for the indications and treatment results, in the event that IDET is introduced in Denmark this should take place via a randomized controlled clinical trial.”

Cochrane Review
Gibson 2005.

The Cochrane review concluded that the effectiveness of intradiscal electrotherapy (IDET) remained unproven.

Agence d' Evaluation des Technologies et des Modes d'Intervention en Sante (AETMIS)
November 2005

In a report prepared for AETMIS, the recommendation was made, "to include this technology as an insured service conditional upon it being used by appropriately trained physicians in medical settings where continuous evaluation and research are conducted and upon the creation of clinical registries for evaluating its effectiveness in Québec." The evidence was considered weak, and at the time of the report it was offered in one private medical clinic in Montréal. Currently the service is not insured in Québec.

ECRI Target Database
June, 2007

The state of the evidence base for intradiscal electrothermal annuloplasty for discogenic pain was rated low for quantity, quality, consistency and robustness. Adverse events for this technology were not well documented. Reimbursement appears to be limited as several local Medicare carriers and major third-party payers deny coverage for the procedure.

3. Internal technology assessment

CMS performed an extensive literature search utilizing PubMed for randomized controlled trials (RCTs) and nonrandomized controlled trials, cohort or case-control studies, case series studies and systemic reviews evaluating the use of thermal intradiscal procedures. The literature search was limited to the English language and specific to the human population, but included studies conducted in all countries, including the United States.

Evidence for TIPs came from three randomized controlled trials, one prospective randomized dosing trial, one case control study, one prospective matched control study, numerous case series studies, two systematic reviews and one meta-analysis. The sponsors provided additional information in addition to the previously mentioned evidence which included: reviews, case reports, cadaver studies, animal studies, and a notebook of investigator biographies.

Evidence Summary

Randomized Controlled Trials

IntraDiscal Electrothermal Therapy

Pauza K, Howell S, Dreyfuss P, et al. A randomized, placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. The Spine Journal 2004;4:27-35.

Pauza reported on 64 patients that were randomized to either IDET (37) or sham (27). The objective of the study was to see if IDET was better than placebo treatment for low back pain of at least six months duration.

Initial inclusion criteria included:

1. Age 18 to 65 years
2. Low back pain present for greater than six months duration
3. Failure to improve after at least six weeks of nonoperative care
4. Low back pain exacerbated by sitting or standing and relieved by lying down
5. A score less than 20 on the Beck depression scale
6. No surgical interventions within the previous 3 months
7. Less than 20% disc height narrowing on lateral plain film radiographs

Initial exclusion criteria included:

1. Previous lumbar spine surgery
2. Abnormal neurological examination other than ankle reflex changes
3. Radicular pain by history or examination
4. Structural deformities such as spondylolisthesis at the painful segmental level
5. Vertebral canal stenosis or scoliosis
6. Intervertebral disc herniations greater than 4mm
7. Sequestered intervertebral disc herniations
8. Concomitant cervical or thoracic pain greater than 2/10 on a VAS
9. Uncontrolled or acute medical illnesses
10. Chronic severe conditions, such as rheumatoid arthritis
11. Ambulatory dysfunction
12. Pregnancy
13. Workman’s compensation
14. Injury litigation

15. Disability remuneration
16. Allergy to contrast media or drugs to be used in the intended procedure
17. Unwillingness to consent to the study

The study was conducted in a private practice in a small city in Texas that specializes in spinal pain. The authors stated, “Between September 2000 and April 2002, patients for the study were recruited from the practice of the senior author, from colleagues and by invitations in local and national television and print media.” There were 4,523 enquiries, but 3,163 patients declined to be randomized or comply with protocol and 1,100 did not meet initial clinical inclusion criteria. This left 260 potentially eligible patients. The potentially eligible patients were screened with discography. The authors stated, “A patient was deemed to have discogenic pain if provocation of an intervertebral disc reproduced their accustomed pain within similar pressure ranges but provided that no pain was reported when adjacent discs were stimulated or during sham pressurizations.” Directly after discography, computed tomography (CT) scan was obtained. The authors stated, “To be eligible for the study, patients had to have a posterior tear of the annulus fibrosus.” Of the original 4,523 patients, 64 were eligible for the study.

Patients were randomized by computer-generated random numbers. Sham treatment patients had an introducer needle placed in position for treatment during conscious sedation. The principal investigator was unblinded at this point. Procedural noise and time passage were similar to the active treatment group. Both groups were dispensed hydrocodone 10mg/acetaminophen 325mg for post operative pain, wore a lumbar corset for 6 weeks and participated in an exercise program from week six to 12. Exercise compliance was assessed by a blinded evaluator. Before treatment and at six months post procedure, the 10-point VAS, the SF-36, and the ODI were used to compare outcomes. Outcomes were assessed by a blinded evaluator. The authors stated, “The primary objective of the study was to compare the improvement in pain and physical function between groups,” so the statistical tests they chose were a group means comparison using a t test for continuous variables and the Fisher’s exact test for categorical variables and frequency distributions. Other post-hoc analyses were conducted, including the proportion of patients at 6 months who obtained varying degrees of pain relief compared to pretreatment levels. The authors admitted that they recruited fewer patients than planned and that the power was reduced from 80 to 60%, but that “60% power was enough to detect the significant differences reported.”

Demographics were reported for 37 IDET patients and 27 sham patients. The mean age for both groups was about 40 years old. While it was stated that there were no relevant statistically significant differences between the groups at inception, 15% of sham treatment versus 8% of IDET treatment were unemployed because of back pain, with 81% of IDET patients working and 63% of patients in the sham group working. Baseline metrics of VAS, SF-36 by subscale, and ODI were reported. The authors commented, “In essence, the patients were reasonably healthy apart from having pain and slight to moderate disability in physical functioning, as seen both on the SF-36 and the Oswestry scale.” Patient blinding was checked within one hour after treatment and was deemed to be adequate at that time. Intention to treat analysis was not done so only 32 patients in the IDET group are reported and 24 in the sham group (Five missing IDET patients: one died, one had poor catheter placement, one had a fractured leg, two had a new injury. Three missing sham group patients: one was non-compliant with follow-up, one had concurrent illness, one had a drug abuse problem and a compensation claim). See Table 1 for main outcomes reported.

Table 1 - Main outcomes of patients who underwent IDET or sham treatment

Outcome measure	IDET (n=32) Mean SD	Sham (n=24) Mean SD	P value*
VAS for pain (0-10)			
Pretreatment	6.6 1.4	6.5 1.9	0.758
6 Months	4.2 2.6	5.4 2.7	0.089
Change	2.4 2.3	1.1 2.6	0.045
SF-36 Bodily Pain (0-100)			
Pretreatment	36 12	35 12	0.765
6 months	53 19	44 20	0.085

Outcome measure	IDET (n=32) Mean SD	Sham (n=24) Mean SD	P value*
Change	17 19	9 15	0.086
SF-36: Physical Functioning (0-100)			
Pretreatment	56 24	49 21	0.236
6 months	71 22	60 24	0.079
Change	15 27	11 17	0.548
Oswestry Disability Scale (0-100)			
Pretreatment	31 10	33 11	0.485

Outcome measure	IDET (n=32) Mean SD	Sham (n=24) Mean SD	P value*
6 months	20 12	28 15	0.023
Change	11 11	4 12	0.050
* p value calculated from t test			

Post-hoc analyses were done that defined absolute change as pain score being worse, same, improvement < 2.0, improvement > 2.0 and relative change as percentage of change (< 0%, 0 - 24%, 25 - 49%, 50 - 74%, 75 - 99%, 100%). The conclusion with this analysis was that there were statistically significant differences in favor of IDET. Another post-hoc analysis was presented that examined the two groups on the basis of baseline outcome measures. The authors concluded, “It emerged that IDET was significantly more effective for patients with pain scores less than 70 at inception and for patients with poor function or greater disability at inception.” There was no statistical adjustment for multiple comparisons or rationale to the cut points.

The authors did not report analgesia use after treatment other than, “None of these patients resorted to any co-intervention or self-medication outside the postoperative analgesics and rehabilitation program that were prescribed.” They did not report specifically any adverse events other than, “No patient had any adverse effects attributable to their treatment.”

The authors concluded, “Nonspecific factors associated with the procedure account for a proportion of the apparent efficacy of IDET, but its efficacy cannot be attributed wholly to a placebo effect. The results of this trial cannot be generalized to patients who do not fit the strict inclusion criteria.”

Freeman B, Fraser R, Cain C, et al. A Randomized, Double-Blind, Controlled Trial Intradiscal Electrothermal Therapy Versus Placebo for the Treatment of Chronic Discogenic Low Back Pain. Spine 2005;30(21):2369-2377.

Freeman reported on 57 patients that were randomized to either IDET (38) or sham (19). The objective of the study was to test the safety of IDET compared with sham treatment for low back pain of at least three months duration.

Eligibility criteria included:

1. Minimum age 18
2. Candidate for IDET procedure at one or two levels
3. Symptoms of degenerative lumbar disc disease of at least three mo duration
4. Failure to improve with a minimum of six wk of conservative treatment (including pain medication and physical therapy)
5. Present with marked functional limitation
6. Sitting intolerance greater than standing intolerance
7. Present with predominant low back pain with or without referred let pain
8. Negative straight leg raise and normal neurologic examination
9. The presence of degenerative disc disease on MRI with global disc degeneration or posterior or posterolateral annular tear evident
10. The presence of one or two level symptomatic disc degeneration as determined by provocative lumbar discography at L3-L4, L4-L5, L5-S1 and with an adjacent asymptomatic control disc
11. At the target level, the discogram and subsequent computed tomography scan should demonstrate contrast spreading to the outer annulus or beyond the confines of the disc
12. Must be willing to comply with follow-up as per the protocol

Exclusion criteria included:

1. Evidence of a large contained or sequestered herniation (small contained herniation is allowed)
2. Loss of more than 50% disc height at the target level
3. Severely disrupted disc (sufficient annular tissue is required for safe catheter placement)
4. Neurogenic claudication due to spinal stenosis
5. Three or more symptomatic lumbar disc levels
6. Previous back surgery at any level of the lumbar spine
7. Spondylolisthesis at a symptomatic disc level
8. Psychological disorders that may impact treatment outcome (e.g., severe depression, drug addiction)
9. Medical condition that could interfere with follow-up care or evaluation
10. Current injury litigation
11. Pregnant women
12. Failure to understand informed consent form
13. Participation in other studies of any kind

Study participants were chosen from consecutive patients of three spine surgeons if they satisfied eligibility criteria. Randomization occurred after catheter placement via sealed envelope by an independent technician who was responsible to covertly connect the catheter if the patient was to receive active treatment. All subjects followed a common rehab program. Patient evaluations occurred at six weeks and six months by an independent investigator. Outcomes measures were recorded at baseline and six months and included the VAS, low back pain outcome score (LBOS), ODI, SF-36, Zung Depression index, the modified somatic perception questionnaire, sitting tolerance, work tolerance, medication, and the presence of any neurologic deficit. Success was defined a priori as a composite measure: no neurologic deficit resulting from the procedure, an improvement in the LBOS of seven or more points, and an improvement in the SF-36 subscales of bodily pain and physical functioning of greater than one standard deviation from the mean. Sample size was calculated before the study and using a 2:1 allocation with 80% power, 75 patients were required. A chi squared test was planned for statistical analysis of the primary outcome and for continuous measures the t test was chosen, with ANCOVA (analysis of covariance) for analyses adjusted for the relevant baseline measures. Only 57 patients were enrolled after 25 months. The authors stated, “A request by the sponsoring company was made to pool our results with a U.S. randomized controlled trial on IDET that had been set up using a modified version of our protocol. This offer was declined because the studies were dissimilar.”

Baseline demographics were comparable. Mean age was about 40 with maximum age reported as 54 years. No co-morbidities were reported. For the IDET group, 50% were working with 10% on disability, whereas 63% of the sham group were working and none were on disability. Two subjects from the IDET group were withdrawn before the end of the study and excluded from the analysis. One was a technical failure and the other underwent fusion for increased pain. In the final analysis of 36 IDET patients and 19 sham patients, no subject in either treatment arm met the composite criteria for success.

Table 2 - Comparison of changes in scores at baseline and at 6 months

Variable	IDET (n= 36) Mean (95% CI)	Placebo (n= 19) Mean (95%CI)	Difference of Means (95%CI)	Pr > |t|
LBOS	-0.971 (-2.337, 0.394)	0.737 (-0.765, 2.238)	-1.708 (-3.824, 0.408)	0.111
ODI	-1.314 (-4.171, 1.543)	0.842 (-6.149, 7.833)	-2.156 (-8.369, 4.056)	0.489
ZUNG	-0.167 (-2.481, 2.148)	0.706 (-3.834, 5.246)	-0.873 (-5.302, 3.557)	0.693
MSPQ	0.286 (-1.533, 2.104)	0.177 (2.733, 3.086)	0.109 -3.036, 3.254)	0.945
SF-36 Physical functioning	2.624 (-2.675, 7.922)	1.579 (-6.416, 9.574)	1.044 (-8.045, 10.13)	0.819
SF-36 Bodily Pain Index	5.056 (-0.799, 10.91)	7.053 (0.963, 13.142)	-1.997 (-11.02, 7.031)	0.659

Results were analyzed by multiple subgroups at the request of the sponsoring company, Oratec, and no clinically important differences were found. Though analgesic use was not mentioned, it was mentioned in two of these subgroup analyses (no access to the data). One group analysis excluded subjects taking narcotic medication at baseline and the other excluded subjects taking eight or more panadeine forte tabs per day at baseline.

The authors reported that no serious adverse events in either arm of the study occurred, without defining serious adverse events. The authors also reported, “Transient radiculopathy (< 6 weeks) was reported in four study participants who underwent IDET and in one study participant who underwent the sham procedure.”

The authors concluded that IDET was no more effective than placebo for the treatment of chronic discogenic low back pain.

Percutaneous Intradiscal RadioFrequency Thermocoagulation

Barendse G, van den Berg S, Kessels A, et al. Randomized Controlled Trial of Percutaneous Intradiscal Radiofrequency Thermocoagulation for Chronic Discogenic Back Pain. Spine 2001;26(3):287-292.

Barendse reported on 28 patients randomized to either radiofrequency thermocoagulation (13) or sham (15) treatment. Recruitment for the trial was from specialist’s referrals to a university hospital of patients with chronic nonspecific low back pain for more than one year.

Exclusion criteria:

1. Patients with radiculopathies and other neurologic abnormalities
2. Younger than 30 or older than 65
3. Spinal stenosis
4. Spondylolisthesis
5. Multilevel burnt out disc lesions
6. Coagulation disturbances
7. Pregnancy
8. “initial “high” visual analogue score less than 5.0”
9. Diabetes mellitus
10. More than one pain syndrome

Patients had a diagnostic block of the dorsal rami to exclude zygapophysial joint pain. Then, discography with anesthesia was performed at L4-L5 and L5-S1 and only those patients who reported good pain relief or no pain 30 minutes after the procedure were selected for the study. If patients had more than one level that was positive they were excluded. Patients who met all the inclusion/exclusion criteria and who consented to participate were randomized to two treatment groups by computer program. The sham group was reported to be treated the same as the treatment group but no current was applied during their procedure. The treating physician was blinded throughout the procedure, with a disinterested third party applying the current after opening of the randomization envelope. Data were obtained by an investigator blinded for the allocation of the patient. Analgesic intake was monitored.

Radiofrequency lesioning was performed giving a 90-second 70°C lesion to the center of the disc. The ODI and the Dartmouth COOP Functional Health Assessment charts/World Organization of Primary Care Physicians chart was scored before treatment and eight weeks after treatment. Success was defined as at least a two point reduction on the VAS and at least a 50% pain reduction on global perceived effect. Patients judged to be a success were also assessed at three, six, and 12 months. Patients who failed treatment by this definition were removed from the study and subsequently offered different treatment options. The primary outcome was the percentage of successes at eight weeks. Success rate comparison included an odds ratio with 90% confidence interval calculated with a logistic regression model. Analyses adjusted for gender, age, duration of pain before treatment, average pretreatment pain intensity, and score after diagnostic nerve block. Secondary outcomes included differences between group changes in VAS score, ODI, use of analgesic tables, and COOP/WONCA chart (international version of Dartmouth COOP chart; WONCA = World Organization of National Colleges, Academies and Academic Associations of General Practices/Family Physicians) and their 90% confidence intervals. Analyses were performed unadjusted with a Student’s t test and adjusted by using a linear regression model.

Between July 1994 and September 1996, 287 patients with chronic nonspecific low back pain were screened. Thirty-seven patients fulfilled all selection criteria, but only 28 entered the trial. Demographics are listed in Table 3.

Table 3 - Study demographics

Variables	Sham group (n=15)	Lesion Group (n=13)
Sex	5 Males, 11 females	5 males, 8 females
Age, mean(SD) yr	45.2 (8.4)	40.8(7.5)
Months of pain, median(range)	38(10-300)	60(8-204)

Variables	Sham group (n=15)	Lesion Group (n=13)
Pretreatment VAS, mean(SD)		
VAS mean	5.5 (1.1)	6.5 (1.3)
VAS high	8.0 (1.3)	8.6(1.1)
VAS low	3(1-6)	4(2-6)
No. of analgesic tablets per 4 days, Median(range)	5 (0-15)	3 (0-19)
ODI, mean(SD)	40.7 (9.5)	43.7(11.6)
L4-L5 level of discogenic pain	6	4
L5-S1 level of discogenic pain	9	9

One patient who was allocated to sham therapy received an RF treatment, so analyses were performed with an intention to treat and as treated. Eight weeks after treatment, there were two treatment successes in the sham group and one in the lesion group. The adjusted and unadjusted odds ratio was 0.5 and 1.1, respectively (not significant). There were no statistically significant differences between the two groups in secondary outcome variables. It was reported that there were no complications during or after the procedure, though complications were not defined.

The authors concluded that percutaneous intradiscal radiofrequency thermocoagulation for 90 seconds at 70°C was not effective in reducing chronic discogenic low back pain.

Prospective Randomized Dosing Trial

Percutaneous Intradiscal RadioFrequency Thermocoagulation

Ercelen O, Bulutcu E, Oktenoglu T, et al. Radiofrequency Lesioning Using Two Different Time Modalities for the Treatment of Lumbar Discogenic Pain: A Randomized Trial. Spine 2003;28(17):1922-1927.

Ercelen reported a study of 39 patients with at least a two year history of chronic low back pain who had failed some kind of conservative therapy and were randomized into two treatment groups evaluating different durations of radiofrequency therapy. According to the authors, patients were included who had various conservative treatments for at least two years, had persistent pain and the qualities of their lives were severely affected (no further inclusion details were identified).

Exclusions were listed as:

1. spinal stenosis
2. instability
3. spondylolisthesis,
4. diabetes mellitus,
5. tumor infiltration,
6. coagulation disorders,
7. clinical radiculopathy,
8. other neurologic abnormalities or systemic inflammatory diseases.

Sixty patients had decreased signal intensity on T2-weithed images on MRI. The criterion for inclusion from this group was positive provocative discography. Out of sixty patients, 39 had positive discography and were entered into the study. Patients were randomized by computer into a group receiving radiofrequency lesioning an 80°C for 120 seconds (Group A, 20 patients) or 360 seconds (Group B,19 patients). Note that one patient in group A had discitis and one patient in group B did not return for follow up and both were excluded from analysis (they were not counted as failures). Other adverse events were not listed. Patients were assessed with VAS by a nurse immediately after the procedure, at one and two weeks, and at one, three and six months after treatment. ODI was assessed before the procedure and at one and six months.

Patient characteristics were listed for 37 patients. The average age of both groups was about 40. Gender, level of discogenic pain, VAS and ODI were similar at baseline. The level of discogenic pain was either L4-L5 or L5-S1. While patients were evaluated for radial and/or circumferential tears, they did not include these as followed parameters. While early scores (one month follow-up or less) showed improvement, at six months there were no statistical differences between the final (six months) and the pretreatment VAS and ODI values in both groups ($P > 0.5$). Also, at six months follow up, there were no statistical differences between the two groups in ODI or VAS. The authors concluded, “The results of this study indicate that the disc radiofrequency lesioning seems to provide short-term relief for a period of 1 month. But this effect cannot be claimed to be significant, because there was no control group to compare. Because the response to pain relief decreased gradually after 1 month, this method is unacceptable as a long-term modality.”

Case Control Studies

IDET

Bogduk N, Karasek M. Two-year follow-up of a controlled trial of intradiscal electrothermal annuloplasty for chronic low back pain resulting from internal disc disruption. The Spine Journal 2002;2:343-350.

Karasek M, Bogduk N. Twelve-Month Follow-up of a Controlled Trial of Intradiscal Thermal Anuloplasty for Back Pain Due to Internal Disc Disruption. Spine 2000;25(20):2601-2607.

Bogduk reported on 53 patients with back pain, 36 of whom were treated with IDET and 17 of whom, due to insurance denial, were treated with other types of treatment. Karasek reported the 12 month follow-up of this group, while Bogduk reported the two-year follow-up. Patients were recruited from a single site private practice referral clinic. Recruitment occurred between May 1998 and November 1998, where 150 consecutive patients were seen in whom back pain had been present for at least three months with no evidence on history, clinical exam or imaging of disc prolapse, neurological disease, tumor or infection. It was stated that a number of conservative measures had been attempted, but did not offer a specific protocol. Forty of these patients were excluded due to multilevel disc degeneration on MRI or clinical features that suggested zygapophysial joint pain, muscle pain or sacroiliac pain. One hundred and ten patients then underwent discography and subsequent CT.

Study inclusion criteria included:

1. Positive provocative discography. For a disc to be positive, infiltration of the disc had to reproduce the patient's pain whereas infiltration of adjacent discs did not.
2. The painful disc exhibited a radial fissure reaching at least the outer third of the annulus fibrosus but with the outer perimeter of the annulus being intact, without communication with the epidural space.

Exclusion criteria included:

1. Less than 80% of expected normal disc height.
2. Significant comorbidity that would confound the assessment of outcome.
3. Previous lumbar fusion.
4. Anatomical abnormalities that would interfere with the procedure.

Of the 110 who met the previous criteria, 53 met the above inclusion criteria. Insurance carriers were contacted and authority was obtained in 36 and denied in 17. The comparison group of 17 "proceeded to a rehabilitation program" that had been the manner of treatment for that practice for patients with discogenic pain. No further details about the program were given. For the treatment group, the electrode was maneuvered into various positions in an attempt to heat the posterior and posterolateral annulus in the region of the radial fissure to a temperature that the patient could tolerate (80° – 90°C) as much as possible. Cefazolin was administered intravenously and intradiscally. Outcome measures were the VAS, return to work and use of opioids analgesics, or "other major interventions." Measures were obtained before treatment and at three months after treatment in both groups, and then only in the IDET group at six, 12 and 24 months. The 17 patients in the comparison group left the practice so could not be followed; however, where possible, "they were contacted to determine their status at 12 months and at 24 months." Success was defined ad hoc as at least 50% reduction in pain, that patients remained or retuned to work, and no longer required opioids for their pain (where they defined opioids as morphine, hydrocodone, or drugs of similar potency, so other analgesics including small quantities of codeine were allowed).

Demographics were reported to be similar for treatment and comparison groups. Median age for the treatment group was 39 years (range 31-50) and 45 years (range 34-49 years) for the comparison group. The median duration of back pain was about 30 months for both groups (interquartile range 12-72 for comparison group, 14-70 for the treatment group), with a VAS for pain of eight (interquartile range of 5-8 for the comparison group and 7-9 for the treatment group). Discs that were judged to be painful included both single level discs (L1-2, L2-3, L3-4, L4-5, L5-S1) and two level discs (L3-4, L4-5; L3-4, L5-S1; L4-5, L5-S1). Interestingly, eight of 17 in the comparison group had workers compensation or motor vehicle accident claims, and 17 of 36 in the treatment group had claims. The results showed little change in median VAS (7.5 at 12 and 24 months) for the comparison group during the 24 month follow-up, though five patients were lost to phone follow-up at 12 months (three received IDET, one died, one refused to provide data) and two more were lost at the 24 month follow-up (could not be contacted). The treatment group maintained a statistically significant decrease in median VAS (3.5 at three months; 3.0 at six, 12, and 24 months) through-out the 24 month follow-up (one patient lost to follow-up at 12months). VAS scores were also examined as percentage change in VAS at three, 12, and 24 months, which the authors referred to as categorical outcomes. The authors reported, “These categorical data, however, are somewhat illusory, because the patients with particular degrees of recovery at one time period are not necessarily the same patients with those degrees of recovery at a following period.” Information of individual VAS scores by follow-up time was provided graphically but not in table form. The graph demonstrated variability in the scores but not necessarily sustained improvement. For the comparison group, only one patient returned to work who was initially not working and of 10 patients working before treatment, three ceased work. They reported that seven in the comparison group still used opioids (follow-up time not given), that five had stopped but four started using opioids. For the treatment group of 35 patients, of 16 patients not working, nine returned to work. Twelve still used opioids at two years. Four patients underwent fusion without subsequent relief of pain. The authors noted that compensation status (i.e., worker’s compensation) was not a determinant of outcome. Given the criteria that the authors defined as success, only one patient in the comparison group met these criteria – though this patient attributed the resolution of her back pain to a hysterectomy that she had at 12 months into the study. At 24 months, the treatment group was said to have a 54% (19 of 35) success rate, though from the global outcome table it appears to be 51% (only 18 of 35 met the no use of opioids criteria). The authors stated that 20% of patients treated with IDET had complete relief of pain, combined with return to work or remaining at work, and no use of opioids, based on the 24 month assessment. The authors concluded, “It is not universally successful, but 54% of patients can reduce their pain by half, and one in five patients can expect to achieve complete relief of their pain.”

Prospective Matched Control Study

Kapural L, Hayek S, Malak O, et al. Intradiscal Thermal Annuloplasty Versus Intradiscal Radiofrequency Ablation for the Treatment of Discogenic Pain: A Prospective Matched Control Trial. Pain Medicine 2005;6(6):425-431.

Kapural matched 42 patients for age, sex, weight, smoking history, manual labor, and number of intervertebral discs treated. However, the authors stated that 21 had radiofrequency and 28 had IDTA which included seven patients that were unmatched. Mean age of patients was 42 years. Co-morbidities other than smoking were not listed. The authors stated, “The study was explicitly a head-to-head comparison of two techniques, by an operator experienced with both. The hypothesis was simply that outcomes would be no different.” Single center-single physician performed all procedures but was not blinded, nor was the patient or outcome assessor blinded. Inclusion criteria were low back pain unresponsive to conservative treatment for greater than six months, no evidence of compressive radiculopathy, no prior surgery, disc height at least 50% of adjacent non-degenerated control disc, no evidence of disc herniation, no signs of lumbar stenosis, no psychological issues, evidence of single-level or two-level disc disease at MRI and positive provocation discography. Exclusion criterion was worker’s compensation. The IDTA group had 90°C maintained for 4 minutes. The PIRFT group had 55°C for four minutes, 60°C for five minutes and 65° C for five minutes. There was no information about co-interventions in either group. Pain was rated by VAS and disability was assessed by the Pain Disability Index (unclear if validated in this population) at 12 months. Results included VAS pain score decreased from 7.4 +/- 1.9 before IDTA to 1.4 +/- 1.9 at one year follow-up while for PIRFT VAS scores decreased from 6.6 +/-2.0 before to 4.4 +/-2.4 at one year. Individual VAS scores were not reported.

Table 4 - The mean pain disability index (PDI) differences

Time	Estimated mean difference in PDI (IDTA-PIRFT)	Lower level 95% CI	Upper level 95% CI	P value
Preprocedure	7.2	-3.0	17.4	0.16
2 weeks	- 0.95	-11.2	9.2	0.85
2 months	-5.2	-15.4	5.0	0.31
3 months	-17.3	-27.5	-7.1	< 0.001
6 months	-16.8	-27.0	-6.6	0.001
9 months	-24.2	-34.4	-14.0	< 0.001
1 year	-21.8	-32.0	-11.6	< 0.001

There was no mention of adverse events, patient follow-up numbers, or who was included in the follow-up tallies (for instance, 28 patients received IDTA; however, were all included in follow-up?). The authors concluded that, “IDTA appears to be more efficacious than RFA based on PDI and VAS scores measured at one year following procedure.”

CASE SERIES

Thirty-one case series are summarized in table format in Appendix B.

Systematic Reviews of IDET and PIRFT

Andersson GB, Mekhail NA, Block JE. Treatment of Intractable Discogenic Low Back Pain. A Systematic Review of Spinal Fusion and Intradiscal Electrothermal Therapy (IDET). Pain Physician 2006;9(3);237-248.

A company-sponsored 2006 systematic review was done that included 18 IDET articles categorized by the authors thusly: 2 randomized controlled trials, 2 non-randomized controlled trials, "11 before-after trials", and 3 case series. These trials were included: Pauza et al. 2004; Freeman et al. 2005; Karasek and Bogduk 2000; Bogduk and Karasek et al. 2002; Derby et al. 2000; Saal and Saal 2000; Saal and Saal 2000; Singh 2000; Welch et al. 2001; Gertzen et al. 2002; Saal and Saal 2002; Spruit and Jacobs 2002; Lutz et al. 2003; Kapural et al. 2004; Mekhail and Kapural 2004; Endres et al. 2002; Cohen et al. 2003; Freedman et al. 2003. They did a historical comparison using selected fusion articles. The authors concluded, "The IDET procedure appears to offer sufficiently similar symptom amelioration to spinal fusion without the attendant complications." None of the studies included in this systematic review were actually head to head comparative studies of the two procedures.

Urrutia G, Kovacs F, Nishishinya MB, Olabe J. Percutaneous Thermocoagulation Intradiscal Techniques for Discogenic Low Back Pain. Spine 2007;32(10):1146-1154.

This systematic review was based on a literature search up to 2005. The methodological quality was independently assessed following the criteria recommended by the Cochrane Back Review Group. Six studies were included: Barendse et al. 2001; Bogduk-Karasek et al. 2002; Ercelen et al. 2003; Freeman et al. 2005; Kapural et al. 2005; Pauza et al. 2004. Urrutia's systematic review focused on IDET and PIRFT as the two percutaneous thermocoagulation intradiscal techniques to treat discogenic back pain. The results from the RCTs showed that PIRFT was not effective for the treatment of discogenic low back pain. For IDET, one RCT showed a positive effect only on pain severity, but the second and best quality RCT showed no effect on any variable. Urrutia noted, "… potentially serious adverse effects have been reported." The authors concluded, "The available evidence does not support the efficacy or effectiveness of percutaneous thermocoagulation intradiscal techniques for the treatment of discogenic low back pain."

Meta-Analysis of IDET

Appleby D, Andersson, G, Totta M. Meta-Analysis of the efficacy and Safety of Intradiscal Electrothermal Therapy (IDET). Pain Medicine 2006;7(4):308-316

A company-sponsored 2006 meta-analysis was done that included 17 articles. These trials were included: Pauza et al. 2004; Bogduk and Karasek 2002; Saal and Saal 2002; Wetzel et al. 2002; Lutz et al. 2003; Derby et al. 2000; Spruit et al. 2002; Gerszten et al. 2002; Singh 2000; Freedman et al. 2003; Lee et al. 2003; Mekhail et al. 2004; Kapural et al. 2004; Cohen et al. 2003; Endres et al. 2002; Webster et al. 2004; Davis et al. 2004. By the author's analysis, the mean improvement in VAS score was 2.9 points, 21.1 points on the SF-36 physical function score, 18 points on the SF-36 bodily function scale, and seven points on the ODI scale. The authors concluded, "Although variation exists in the reported outcomes among the various studies of the IDET procedure, the pooled results of the published studies provide compelling evidence of the relative efficacy and safety of the IDET procedure."

Adverse events

While there is no comprehensive database of adverse events for TIPs, several case reports and a review gave indications of possible events. In 2007, Kapural and Cata reviewed the complications of percutaneous techniques used in the diagnosis and treatment of discogenic lower back pain. They provided a list of these possible complications:

Infectious
Discitis
Epidural abscess
Vertebral osteomyelitis
Subdural empyema
Bacterial meningitis
Neural
Cauda equine syndrome
Nerve root damage – causalgia
Acute disc herniation
Allergic/immune hypersensitivity
Dye-induced anaphylaxis
Urticaria
Vascular
Retroperitoneal bleeding
Intramuscular hematoma
Others
Probe-electrode fracture
Muscle spasm

Diagnostic tests for thermal intradiscal treatments include provocative discography, so the risks of this procedure must be considered. The reported discography complication rate ranges from 0 to 2.5% (Kapural and Cata 2007). Discitis, epidural abscess and bacterial meningitis have all been reported (Kapural and Cata 20027). Acute lumbar disc herniations have also been reported (Kapural and Cata 2007). For IDET, Kapural and Cata suggested a reported range of 0% to as high as 10%, though one series reported 15% (Cohen et al. 2003). Davis was reported to have had one episode of discitis out of a case series of 44 patients (Davis, Delamarter et al. 2004). Orr reported a patient who underwent IDET at another center where the catheter tip that broke off inside the disc space had migrated to an intradural position that lead to a sensory neuropathy that improved but did not resolve after removal (Orr and Thomas 2005). Boswell reported a patient who underwent attempted discography and IDET that was complicated by at least two lumbar dural punctures (Boswell and Wolfe 2004). Post procedure, the patient developed severe back pain and then intractable seizures and coma. The patient could not be resuscitated and expired. It was concluded that the patient succumbed from an unintentional dose of intrathecal cefazolin which was in the contrast agent used to confirm needle placement (Boswell and Wolfe 2004). Orr stated, “The rationale that this procedure is justified because it is low risk and relatively noninvasive may need to be reassessed” (Orr and Thomas 2005). Hsia reported on a patient who experienced cauda equine syndrome from IDET after the catheter was inappropriately placed in the spinal canal (Hsia, Isaac et al. 2000). Six months post procedure the patient continued to require daily urinary self-catheterization and had bowel incontinence (Hsia, Isaac et al. 2000). About IDET Hsia noted, “This population may, in fact, not benefit from expensive or aggressive therapies.” Ackerman as well reported a patient who developed cauda equina syndrome after IDET (Ackerman 2002). He noted that both cases of cauda equina were not reported by the treating provider (Ackerman 2002). Ackerman stated, “The IDET procedure is relatively new, and complications possibly related to it may not be readily reported because of potential litigation.” Cohen reported on a patient who had a giant herniated disc following IDET (Cohen, Larkin et al. 2002). The patient proceeded to undergo lumbar fusion for pain and radicular symptoms. Scholl and Djurasovic each described a case of vertebral osteonecrosis related to IDET (Scholl, Theiss et al. 2003; Djurasovic, Glassman et al. 2002). Djurasovic’s report described a patient who developed vertebral body osteonecrosis associated with the use of IDET (at another clinic) which led to incapacitating back pain that required surgical fusion (Djurasovic, Glassman et al. 2002). For discTRODE, there were no complications published in three studies and for intradiscal biacuplasty, out of about 100 cases, only a few patients reported transient back pain.

4. Medicare Evidence Development and Coverage Advisory Committee (MedCAC) Meeting.

CMS did not hold a MedCAC meeting on this topic.

5. Evidence-based guidelines

CMS identified three evidence based guidelines that addressed TIPs.

The American Society of Interventional Pain Physicians (ASIPP) guideline *Interventional Techniques: Evidence-based Practice Guidelines in the Management of Chronic Spinal Pain* (Boswell, Trescot et al. 2007) included a review of both IDET and radiofrequency posterior annuloplasty (RFA) for the treatment of discogenic pain from internally disrupted intervertebral disc as an alternative to major surgical intervention. This represented an update of previous guidelines put out by ASIPP. In the evaluation of these procedures, less than six months was equated to short term relief and six months or more was equated with long term relief.

In reference to IDET, the authors stated, "…the mechanism of action of IDET has not been established." Some of the assumptions of mechanism of action proposed in the guideline were that heating the annulus may serve to strengthen the collagen fibers, seal fissures, denature inflammatory exudates, or coagulate nociceptors. The review of the evidence for IDET included one positive randomized trial, one negative randomized trial, seven positive prospective evaluations and two negative reports. The authors evaluated the level of evidence for IDET as moderate for managing chronic low back pain.

For the RFA procedure, also identified by the name of the device (discTRODE), the authors evaluated the level of evidence as limited for short-term improvement, and indeterminate for long-term improvement in the management of discogenic low back pain. The studies identified for RFA were two prospective evaluations.

The *European guidelines for the management of chronic nonspecific low back pain* (Airaksinen, Brox et al. 2006) included a review of intradiscal radiofrequency thermocoagulation (IRFT) and IDET. The authors identified that the diagnosis of IDD was surrounded by controversy. In addition, the effect of IDET was not well understood.

The authors summarized the evidence as follows.

- "There is conflicting evidence that procedures aimed at reducing the nociceptive input from painful intervertebral discs using either IRFT or IDET, in patients with discogenic low back pain pain, are not more effective than sham treatments (level C).
- There is limited evidence that RF lesioning of the ramus communicans[2] is effective in reducing pain up to 4 months after treatment (level C)."

The recommendation for these procedures was stated as;

"We cannot recommend the use of Intradiscal radiofrequency, electrothermal coagulation or radiofrequency denervation of the rami communicans for the treatment of either nonspecific or "discogenic" low back pain."

The International Spine Intervention Society (ISIS) guideline, *Practice Guidelines Spinal Diagnostic & Treatment Procedures* edited by Nikolai Bogduk (2004) on behalf of ISIS standards committee, included a chapter on IDET but did not address other thermal intradiscal procedures. The ISIS guideline categorized IDET as an established procedure which it defined as "…those procedures for which there is reasonable, if not abundant, evidence of validity and utility, or efficacy; or procedures which, although lacking strong evidence, are nonetheless commonly practiced and for which there are no alternative procedures." While it did not identify IDET as one of the latter, discography was listed as such.

The guideline did not specifically categorize the strength of the evidence but did make reference to a number of published articles on IDET some of which were authored by members of the ISIS standards committee chaired by Kevin Pauza, MD. It was stated that, “The present Practice Guidelines do not pretend to be a systematic review of the literature concerning the various procedures addressed.” However, they went on to state that the Standards Committee “endeavored to remain faithful to the rules of evidence.” Rather than utilizing electronic literature searches, the Committee relied on personal libraries of authors and other members with experience in the procedures.

The guidelines provided a history of IDET as controversial due to the lack of controlled studies and the financial interests of persons conducting the initial studies. It identified the contentious rationale that was put forth as the mechanism for action and the lack of evidence to support any of the contentions. Both randomized controlled trials were referenced (the Freeman et al. study which was referenced as Fraser et al. and the Pauza et al. study). One study showed no difference in effect from the treatment group to sham control group (Freeman et al.) and the other study showed no significant differences between groups for mean scores for pain and physical function, but with significantly better Oswestry disability scores for the IDET group (Pauza et al.). The efficacy of the IDET procedure was identified as modest.

The guideline stated that the indications for IDET differed since the operators used different criteria, however all concurred on the diagnosis of discogenic pain determined by discography. The differences between the operators were identified as the diagnostic criteria for a positive discogram, preservation of disc height and the use of CT-discography. The need for CT-discography was identified as being the most contentious issue. It was also stated that while the literature points to application of stringent patient selection criteria for internal disc disruption to achieve the best long-term outcomes, other studies showed comparable outcomes “irrespective of differences in inclusion criteria.”

The guideline stated, “Which criteria should be applied remains a matter of operator-choice. The ideal indications for IDET have not been established.” Numerous contraindications were listed and with respect to patient selection it was stated, “Patients suitable for IDET should be ones who satisfy the diagnostic criteria for discogenic pain or for internal disc disruption, and who do not exhibit any of the contraindications. In essence, they will be patients with back pain, with or without somatic referred pain, free of co-morbidity that might interfere with the safe execution of the procedure or its outcome.”

6. Public Comments

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

Initial Public Comments

CMS received 84 comments during the 30 day public comment period. Four national professional societies provided comments. One comment was submitted by a manufacturer of a thermal intradiscal system. Sixty-two comments were identified as being from physicians (three of which were on behalf of two state professional societies), ten comments were from employees of physician practices (eight were identified as employees of the same physician practice) and seven comments were from the general public. The complete text of the comments is available on the CMS website at http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=215 . Two comments were not posted to the web because they contained personal health information.

A. National Professional Societies

CMS received comments from four national professional societies. Three of the societies recommended coverage for IDET and one society made no recommendation for coverage but recommended strict criteria if there was coverage for IDET. Two societies felt there was insufficient evidence to recommend coverage for the non-IDET thermal techniques. A summary of theses comments is provided.

The American Society for Interventional Pain Physicians (ASIPP) submitted a comment and referred to the ASIPP guidelines published in 2007 (Boswell, Trescot et al.). The guidelines addressed IDET and annuloplasty. They stated, “Our conclusions, based on the published evidence, was that there was moderate evidence to support the efficacy and cost effectiveness of IDET in the treatment of discogenic pain.” (Note: CMS addresses this guideline in Section VII.B.5 of this document.) ASIPP proffered that IDET provides an alternative to spinal fusion. It was further stated, “The cost effectiveness and minimally invasive nature of the percutaneous disc procedures being reviewed should shift the balance of support for the use of percutaneous thermocoagulation intradiscal techniques over the more invasive, more expensive and higher risk spinal fusion surgery.”

CMS also received separate comments from NASS, the American Academy of Pain Medicine (AAPM) and the International Spine Intervention Society (ISIS). These three comments were very similar and at times identical in content. The comments from these societies were based on their review of the literature which specifically addressed IDET. The commenters felt it was important to distinguish IDET or resistance coil heating methods and other intradiscal thermal technologies. NASS pointed out that the evidence for these distinct technologies differed while AAPM and ISIS pointed out that other emerging technologies, radiofrequency intradiscal thermal procedures, are differentiated under CPT Category III codes.

AAPM and ISIS both stated, “although clinical data from RCTs are typically felt to represent the highest standard of evidence in medical literature, the results of RCTs are critically dependent on study design and patient selection criteria.” Both societies felt the two published RCTs on IDET differed in design, patient selection and inclusion criteria as well as outcomes. NASS commented that even though the two prospective double-blind randomized placebo controlled trials on IDET were not directly comparable due to their methodology and patient selection differences, these types of RCTs “are the criterion standard in demonstrating clinical efficacy.” NASS stated “These two studies reach conclusions that differ from the results of earlier cohort studies.” All three societies provided a summary of the Pauza and Freeman studies. (CMS summarizes the Pauza et al. 2004 and Freeman et al. 2005 in the evidence analysis section of this document.)

All three societies referenced a meta-analysis of IDET literature (Appleby et al. 2006) that concluded that despite the variations in the reported outcomes from various studies of IDET, the pooled results of published studies “provide compelling evidence of the relative efficacy and safety of the IDET procedure.” It was noted that both NASS and ISIS identified that funding for this meta-analysis was linked to the manufacturer of the IDET device, Smith & Nephew Endoscopy.

All three societies also referenced a systematic review (Anderson et al. 2006) which concluded that “the IDET procedure appears to offer sufficiently similar symptom amelioration to spinal fusion without the attendant complications.” NASS stated that this study was also funded by Smith & Nephew Endoscopy. NASS also submitted, “Contrasting these views, a third recent review on IDET by Freeman concluded “the evidence for the efficacy of IDET remains weak and has not passed the standard of scientific proof [Freeman 2006].” All three societies noted that there are no published studies regarding IDET in the specific Medicare population.

Both AAPM and ISIS commented that the bulk of the literature reviewed regarding IDET “demonstrates a modest response in well-selected patients.” All three societies noted that the early study optimistic results on IDET were contradicted by the RCTs by Freeman and Pauza.

Both AAPM and ISIS concluded, “that an optimal treatment (surgical, conservative, or minimally invasive) for chronic low back pain of disc origin which provides patients a greater than 50% likelihood of near-complete to complete relief (75%-100%) remains elusive at this time.” In addition, they felt, “Intradiscal thermal lesioning utilizing a resistance-coil heating element placed along or within the posterior disc annulus affords a likelihood of high-grade relief of chronic low back pain in well-selected patients with discogenic low back pain.” They also commented that the risks and costs are greater with open surgical procedures than with IDET.

NASS stated “Overall, the systematic reviews and similar assessments of the literature on IDET are problematic given a variety of methodological issues and the limitations of the literature base.”

ISIS recommended, “that IDET continue to be covered with the following restrictions:

- IDET is only considered in patients with functionally limiting chronic low back pain
- Other potential structural causes of chronic low back pain have been excluded
- The diagnosis of disc pain has been competently established with controlled provocative pressure discography
- IDET, if performed, is limited to discs which show minimal degenerative changes (reduction in disc height less than or equal to 20% of normal)
- IDET not be utilized for the treatment of primary radicular pain or radiculopathy
- IDET not be performed in patients with somatization disorders or other psychological conditions correlated with higher false-positive rates on pressure discography or poor clinical outcomes from other surgical interventions."

NASS did not make a recommendation for coverage of IDET but stated, "If IDET is performed, NASS recommends that strict inclusion criteria be followed" referring to the work by Pauza et al. 2004 and Bogduk et al. 2005. The criteria were essentially the same as those recommended by ISIS.

Both AAPM and ISIS commented that in regard to other non-IDET intradiscal thermal techniques the evidence was insufficient to recommend coverage for these emerging technologies.

B. General Public Comments

Fifty-five commenters supported coverage specifically for IDET, five supported coverage specifically for biaculoplasty, two supported coverage for both IDET and biaculoplasty, one supported coverage specifically for PIRFT and one supported coverage for PDD. The remaining sixteen commenters generally supported coverage of TIPs. One of the commenters who supported coverage for IDET stated that biaculoplasty and PIRFT were investigational. Twenty-one commenters stated that coverage should be for properly selected patients.

Two commenters, on behalf of the Florida Society of Interventional Pain Physicians, provided references to the guidelines published by ASIPP and additional published articles with an article summary included. Also, one commenter on behalf of the Connecticut Pain Society referenced the ASIPP guidelines and the recommendation offered from their society was in favor of coverage for IDET with refined patient selection criteria.

A number of the physician commenters provided their own data and many made reference to published articles. A consultant involved in the publication of a number of articles on IDET concurred with the ASIPP guidelines and provided his own data.

One commenter stated that IDET was over applied early on and did not have significant success rates. However, they viewed biaculoplasty as a significant advancement in the application of thermal energy and saw the only drawback as the limitation of the appropriate diagnosis of discogenic pain. Another commenter felt strongly that biaculoplasty warranted a place in the armamentarium of procedures available to interventional pain physicians. Additionally, a commenter felt that IDET and biaculoplasty, when properly administered, were a tremendous tool for improving comfort and function and decreasing healthcare utilization.

Two comments that were duplicates offered the recommendation, “Medicare cover IDET or let local carriers continue to issue local policies.” While another commenter stated in response to the criticisms of IDET, “…it is not going to be effective in a high percentage of pts, but even a small percentage would make a big difference in quality of life.” Another commenter supported IDET and stated, “…that while data seems to suggest that the procedure may only provide modest improvement, IDET is less destructive, cheaper, and safer alternative that other invasive therapies.”

While one commenter who preformed IDET reported variable results but supported coverage, another commenter offered that IDET had an excellent risk/benefit ratio with a low risk of complication and proven efficacy. Yet another commenter felt that IDET, as a minimally invasive procedure, was well tolerated by the elderly and, for many, their only option.

A commenter stated that if there were more favorable coverage policies in place they would have performed many more IDET procedures. This sentiment was echoed by another commenter who felt that percutaneous thermocoagulation techniques and patients would benefit from “more mainstream acceptance by insurance carriers.” One commenter felt that IDET was the only “well established percutaneous treatment for discogenic pain.”

One commenter felt that thermal therapy was the best choice for a subset of patients and went on to say that improvements in diagnosis and the selection of a narrower subset of patients for these therapies would result in an improvement of outcomes. One commenter stated that they found PIRFT to be safe and effective for discogenic lumbar pain and one commenter supported plasma disc decompression.

While many commenters pointed to the Pauza study as proof of efficacy for IDET, one commenter supported coverage for IDET but felt that although the results of this study showed promise the study had significant flaws. This commenter offered criticism of the patient screening and felt that the manufacturer should make alterations to the catheters. This commenter, a physician who performs IDET, also had the procedure. Two commenters, although supportive of IDET and Biacuplasty, stated that the poor outcomes for IDET have been due to poor studies and/or improperly selected patients.

C. Comments with Evidence

Many of the public comments provided references to published articles (See Appendix D for a list). CMS reviewed all the references and all publications that were considered relevant to this topic are included in the bibliography for this document.

VIII. Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Social Security Act §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” § 1862(a)(1)(A). This section presents the agency’s evaluation of the evidence considered and conclusions reached for the assessment questions.

Our analysis focused on the following question:

Is the evidence sufficient to conclude that TIPs will improve health outcomes in the Medicare population with low back pain?

Percutaneous thermal intradiscal procedures are proposed treatments for chronic low back pain believed to emanate from the cartilaginous spinal disc. After a review of the evidence, CMS believes that the various techniques utilized for TIPs use the same function - the use of heat, seeking the same desired outcome - relief of pain. Some techniques have a greater representation in the published literature; however, the similarities of function and desired outcome are sufficient to support generalizing the available published evidence across all the techniques used in TIPs.

Low back pain symptoms are common, generally vague and of uncertain cause. Most patients will recover over time with supportive care though some may suffer repeated relapses throughout their lifetimes. For patients who seek help an accurate diagnostic test to determine the exact cause of low back symptoms has yet to be developed, creating a source of frustration and opportunity. These present uncertainties have created confusion for both clinicians and patients, as Haldeman stated, “Patients with chronic low back pain (CLBP) are finding it increasingly difficult to make sense of the growing list of treatment approaches promoted as solutions to this widespread problem”(Haldeman and Dagenais 2008a). Treatment approach varies based on theoretical ideas.

The theoretical mechanism of action that these procedures relieve pain by, denervating nociceptors in the posterior annulus fibrosus and stabilizing the disc by collagen modulation, remains unsubstantiated (An, Boden et al. 2003). Cohen noted, “If only nociceptive denervation were responsible for pain relief, one would expect to see rapid improvement after IDET, not the slow, progressive reduction in pain that typically follows a successful procedure” (Cohen, Shockey et al. 2002; Chou, Lew et al. 2005). Additionally, one would not expect any pain relief from repeat procedures, which are in fact performed (Cohen, Shockey et al. 2007). Another hypothesis is collagen modification which alters the biomechanics of the functional spinal segment. However, Lee did not report any change in the stability of the lumbar spine segment before and after treatment with IDET (Lee, Lutz et al. 2001). Also, Kleinstueck found the IDET catheter to be unable to generate sufficient heat to even produce the theoretical collagen changes (Kleinstueck, Diederich et al. 2001). Furthermore, Narvani studied the effect of IDET on the resolution of asymptomatic HIZ (Narvani, Tsiridis et al. 2003b). Six months post-procedure, repeat MRI revealed that there was no resolution of HIZ (Narvani, Tsiridis et al. 2003b).

The devices used in TIPs generally apply radiofrequency energy to generate heat within the disc space. In 2004, Deyo reported, “Most new devices are approved by demonstrating ‘substantial equivalence’ to a product that was marketed more than 25 years ago (before 1976). For this type of approval, a device need only do technically what it claims and be reasonably safe. A device that delivers electric current to the skin can be considered ‘effective’ without asking if it relieves symptoms” (Deyo 2004).

The devices for discogenic back pain in the TIPs’ category utilize the transfer of energy to heat in the cartilaginous disc to treat back pain. All of these devices passed through the FDA under 510(K), meaning that they were found to be substantially equivalent to previous devices without the requirement of clinical trials. The TIPs devices are typically submitted as predicate devices of each other (e.g., the Oratec EndoTAC Monopolar Cautery Probe was the predicate device for the SpineCATH, the SpineCATH was the predicate device for Radionics RF Disc Catheter Electrode System, etc.). The Oratec EndoTAC Monopolar Cautery Probe was found to be substantially equivalent to devices marketed prior to 1976. The product code GEI, 21CFR§878.4400, is identified as an electrosurgical cutting and coagulation device and accessories intended to remove tissue and control bleeding by use of high-frequency electrical current, in effect describing electrocautery. Cauterization as a medical treatment has been in existence since ancient times – heating a piece of metal and applying to an open wound.

While there are claims that the devices in this category that utilize the basic principle of energy transfer are of different design, there is no evidence of significant outcome difference. The evidence does not demonstrate improved health outcomes from the use of TIPs devices in the treatment of back pain that is believed to be coming from the disc.

Uncertainty exists in the selection of appropriate patients for the various procedures to treat low back pain that is suspected to be caused by the disc. Patient symptoms alone do not accurately point to the disc as the source of pain. Identifying the pain generator in low back pain is challenging due to the anatomic complexity of the spine and poor understanding of neurophysiologic mechanisms of pain sensation (Haldeman 1999). TIPs literature maintains that for clinicians to identify patients appropriate for the procedures, positive provocative discography and either MRI and/or CT indicating IDD (or disease) should be relied on. However, the value of discography as a diagnostic tool in the identification of discogenic pain is controversial (National Board of Health, Danish Centre for Evaluation and Health Technology Assessment 2003). The benefit of discography and abnormalities in imaging studies in guiding a patient's treatment for back pain is questioned. Patients with nonspinal back pain and asymptomatic patients can have positive discography (Carragee, Tanner et al. 1999; Carragee, Chen et al. 2000). Additionally, in patients with low back pain, provocation discography can be positive in the absence of imaging structural or physiologic abnormalities (Chou, Lew et al. 2005). While imaging studies can demonstrate structural and physiologic abnormalities, there is no correlation with either the presence or severity of low back pain (Chou, Lew et al. 2005). In fact, patients can have annular tears on MRI or CT and be asymptomatic. Chou stated, "Although a bright, focal increase of T2-weighted magnetic resonance signal in the posterior annulus (the so-called high intensity zone lesion) is correlated with annular tears, it is not correlated with low back pain" (Chou et al. 2005). Slipman showed no statistical correlation between the side of the patients' concordantly painful annular tear and the side of the patients' low back pain during discography (Slipman, Patel et al. 2001). This directly questions if the annular tear, whose natural history is unknown, is the pain generator being tested during discography (Djurasovic, Glassman et al. 2002). In summary, the effect that discography has on patient outcomes (mediated through the choice of therapy) is uncertain and no specific anatomic lesion has been proven to be the source of discogenic low back pain (Rhyne, Smith et al. 1995).

TIPs are promoted as an alternative to more invasive surgery when other treatment modalities for CLBP have failed. However, there are a wide and ever-growing variety of treatment options that include activity modification, multiple pharmacological options, various types of massage, manipulations, medication assisted with manipulation, many types of exercise, multiple physical modalities, educational and psychological training, many types of injections, lifestyle therapies, and complementary and alternative therapies (Haldeman and Dagenais 2008b). It is not clear which or how many of these other treatment modalities that are less invasive (with less adverse effects) than TIPs should be offered beforehand. Furthermore, there is no evidence that TIPs are an alternative to more invasive surgery, particularly fusion. These devices are used by a variety of health care practitioners (Djurasovic, Glassman et al. 2002). Djurasovic noted, "The concept that IDET is an alternative to interbody fusion surgery assumes that the treating physician has experience in selecting patients for this procedure. In the patients described in this report, fusion surgery was advised against by two different consulting surgeons. This raises the question of whether invasive treatment of any sort was indicated" (Djurasovic, Glassman et al. 2002). For instance, Pauza himself noted that the patients in his study population had only slight to moderate disability, as judged by SF-36 and ODI (Pauza, Howell et al. 2004). These patients can hardly be judged as fusion candidates based on this assessment. Though fusion is possible after failed TIPs, the results of fusion after a failed procedure remain unknown (Djurasovic, Glassman et al. 2002). Additionally, which surgical procedure is best after failed TIPs is unknown (Djurasovic, Glassman et al. 2002). Unless patients are randomized to either fusion or TIPs, bias in patient selection can exist, as patients who do not chose surgery may have less severe conditions and may be more apt to improve (Rhyne, Smith et al.1995).

Two of the three randomized placebo controlled trials (Freeman, Fraser et al. 2005; Barendse, van den Berg et al. 2001) demonstrated no benefit of this therapy. The results of the third trial (Pauza, Howell et al. 2004) did not demonstrate positive results that could be translated with confidence to the Medicare population for the following reasons:

- From 4523 prospective patients, only 1.4% (64 patients) were ultimately randomized.
- Inclusion/exclusion criteria effectively excluded the Medicare population.
- Even with this highly selected group, 50% of patients had no benefit.
- Pauza stated, "The results of this trial cannot be generalized to patients who do not fit the strict inclusion criteria."
- Success criteria for pain reduction was defined post-hoc (Urrutia, Kovacs et al. 2007).
- It is unclear that the definition of success that the authors used was clinically meaningful.
- IDET and control groups were not equivalent at baseline, favoring IDET.

- The effect of co-interventions were not included in the analysis (Urrutia, Kovacs et al. 2007).
- The effect of analgesics was not mentioned.
- Even with this small study size, 12.5% of patients were not included in the analysis.
- Numeric differences between treatment and control groups did not appear to be clinically significant, even though two measures were of statistical significance.

Variable definitions of success cloud interpretation of the studies and make direct comparisons difficult. Work groups of experts have advocated for inclusion of standardized measures in five areas: function, symptoms, general health status, work disability and satisfaction with care. The two most important clinical outcomes in the Medicare population are standardized measures of pain and back specific function. No one CLBP measure has yet been devised that is acceptable as a primary outcome measure due to the little understood, complex nature of the disorder. Left to the choice of the investigator, the primary outcome measure(s) can significantly influence success rates. Critics of the Freeman trial disparage it because no patient met the success criteria, in contrast to Pauza, where nonspecific effects were demonstrated. Freeman admitted surprise that there was apparent lack of effectiveness in both groups, but offered as a possible explanation that patients had undergone an exercise program before the intervention, and that IDET was considered by some to be most effective when combined with an intensive exercise program. He hypothesized that it may be that the exercise program was the major component of the perceived success of IDET. Additionally, Freeman defined success a priori, whereas Pauza established his success criteria for pain reduction post hoc – after the results were known (Urrutia, Kovacs et al. 2007). The criteria between the studies are not the same, so comparison is not direct. Barendse, though a small study, suggested that the PIRFT procedure was no better than sham. The follow-up to Barendse was Ercelen where he tried two different techniques to see if this made a difference: It did not.

Two nonrandomized trials (Bogduk, Karesek et al. 2002; Kapural, Hayek et al. 2005) showed positive results for IDET compared with rehabilitation and PIRFT. Neither trial had blinding and both had major sources of uncontrolled confounding. In the trial comparing IDET to rehabilitation, the control group wanted IDET but did not get it due to insurance problems and were pursuing litigation to have the procedure done (Urrutia, Kovacs et al. 2007). All patients in the control group failed to follow-up at that practice, so expectations would be for a poor outcome, particularly considering the strong influence of expectation response in pain treatments. Other potential confounders were not measured (Urrutia, Kovacs et al. 2007). In the small trial (Kapural, Hayek et al. 2005) comparing IDET to PIRFT, patients were matched on various characteristics but uncontrolled confounding was still likely.

The results of these trials aren’t generalizable to the Medicare population. The mean age of the patients in the studies was between 40 and 50 years. Only one study listed co-morbidities such as diabetes. Most studies excluded patients who had a medical condition that would interfere with follow-up, yet did not clearly define this exclusion.

The remaining clinical studies on TIPs are case series, which are particularly problematic in the evaluation of low back pain treatments for the following reasons: the natural history of the syndrome of discogenic pain is unknown, so we can't know when, if and how much a patient will improve without treatment; there is regression to the mean in the study of pain, meaning pain has a tendency to wax and wane over time; the placebo effect, also known as expectation response, plays an important role in the treatment of pain. Therefore, biases and confounding are to be expected in these studies. Case series results overall have been mixed, with the best results by the IDET inventors Saal and Saal (58 patients) reporting a three point decrease in the VAS over an average of 28 months, and the worst reported results by Webster (142 patients treated with IDET) with 22.5% having subsequent surgery during follow-up and unchanged narcotic use over an average of 22 months. The TIPs case series studies are incomplete in reporting on patients, which can be confusing. Studies were reported in abstracts but not yet published, including some rather large studies (over 1,000 patients) (Scholl, Theiss et al. 2003), which indicates a need to accord them lower weight as evidence. We found other studies appear to be reported but with notable differences from the earlier abstract. For instance, Maurer 2008 with 56 patients (patients enrolled between April 1998 and October 2002) resembles an abstract from NASS 16th Annual Meeting (Maurer and Squillante 2002) where 78 patients are reported somewhat differently. Some articles referred to a prospectively collected database (Derby, Lee et al. 2004), or a "nationwide registry" initiated in 1998 by the sponsor to study outcomes through a two year post procedure follow-up (Thompson, Eckel 2002), which caused one to wonder who was included in the published articles and why. There appears to be a lack of independence among some studies, meaning that the same patients may be reported in more than one study, without this being clearly disclosed (Davis, Delamarter et al. 2004). For instance, in 2001, Welch, Gerszten, and McGrath reported on 23 patients that are very similar to the 27 patients in the 2002 article by Gerszten, Welch, McGrath, and Willis. The studies could provide evidence of safety, but not all included studies reported on complications, and those that did used definitions provided by the authors as opposed to a standard, so it is unclear how much safety information these case series studies provided.

Adverse events were poorly characterized, and not reported at all in some studies. Using various definitions of adverse events made interpretation and comparison difficult. Some patients required subsequent surgery (as high as 22.5% in one case series) during follow-up, and it was not clear if this was due to treatment failure or adverse events. The case reports of cauda equina syndrome, vertebral osteonecrosis, and giant herniated disc were concerning. Despite the availability and reported high volumes of the procedure in the United States since the late 1990s, there are no long term safety data. The true scope and incidence of problems is not known.

Andersson's systematic review (Andersson, Mekhail et al. 2006) and Appleby's meta-analysis (Appleby, Andersson et al. 2006) used poor quality studies to arrive at erroneous conclusions. Incompletely reported case series were included, and the systematic review (Andersson, Mekhail et al. 2006) mistakenly included the same patient population reported in several articles. As discussed above, case series studies do not provide adequate evidence of health benefits from TIPs. The systematic review last author (and correspondence author) was a paid consultant (Andersson, Mekhail et al. 2006), and the first author (and correspondence author) of the meta-analysis was a sponsor employee (Appleby, Andersson et al. 2006).

Financial disclosure is not mentioned in some of the published articles, or is difficult to readily interpret (for instance conflict of interest reported as a category that is a number). Nondisclosure suggests that there may be something to hide, whether there is or not (Anderson, Boden et al. 2002). Importantly for patients who receive advice on treatments, the editors of *Spine*, stated, "In other words, financial conflict often skews the results of clinical and basic research toward favoring the drug or device in question." Well-designed, high-quality clinical trials must address both the complexities and biases, real and/or perceived, that exist. This includes the potential biases from funding sources. Shah's retrospective review of articles published in the journal *Spine* identified, "industry supported studies had a greater frequency of positive results than studies with any other funding sources"(Shah, Albert et al. 2005). Weinstein et al. noted, "An important concern is that many conflicts are not currently disclosed" (Anderson, Boden et al. 2002). Nondisclosure by investigators continues to occur (Henschke 2008; DeAngelis 2008). The public's current concern is reflected by the Institute of Medicine's convening a committee on conflict of interest in medical research, education and practice to develop a consensus report.

Conclusion

Identifying the pain generator in low back pain is challenging due to the anatomic complexity of the spine and poor understanding of neurophysiologic mechanisms of pain sensation (Haldeman 1999). There is no convincing evidence that current diagnostic techniques are helpful in patient management. The growing incidence of nonspecific low back pain in the Medicare population (Weiner, Kim et al 2006) in the face of a lack of self-assessed improvement in the patient population with spine problems (Martin, Deyo et al. 2008), despite the rapid progression and adoption of new technologies to the spine market, causes great concern. When examining treatments for chronic low back pain, clinical trials with a placebo comparator and consensus recommended standardized measures that reflect the complexity of the disorder are most helpful for evidence of clinically meaningful benefit.

For TIPs, the mechanisms of action remain theoretical. A thorough review of the empirical evidence on TIPs is adequate to demonstrate the lack of benefit to health outcomes from these procedures. Two RCTs provided evidence of no benefit to health outcomes and one RCT failed to demonstrate confidence of any benefit to the Medicare population. The quality of many of the other studies is disappointing and the lack of sufficient documentation of adverse events and long term outcomes is disconcerting. Therefore, we propose that TIPs are not reasonable and necessary.

IX. Proposed Decision

The CMS proposes that the evidence is adequate to conclude that thermal intradiscal procedures do not improve health outcomes. Therefore, CMS has determined that thermal intradiscal procedures are not reasonable and necessary for the treatment of low back pain and we propose to issue a national noncoverage determination for TIPs.

Appendices [PDF, 526KB]

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[1] Nociceptors are free nerve endings, found throughout the body including the annulus fibrosus portion of the intervertebral disc, which act as sense organs that send signals that cause the perception of pain in response to potentially damaging stimulus.

[2] Ramus communicans is any of the bundles of nerve fibers connecting a sympathetic ganglion with a spinal nerve.

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Bibliography

Ackerman WE. Cauda Equine Syndrome After Intradiscal Electrothermal Therapy. Letter to the Editor. Regional Anesthesia and Pain Medicine 2002 Nov/Dec;27(6):622.

Agence d' Evaluation des Technologies et des Modes d'Intervention en Sante (AETMIS), Quebec. Intradiscal electrothermal therapy for discogenic low back pain. November 2005. Link to web page:
http://www.aetmis.gouv.qc.ca/site/250.403.0.0.1.0.phtml (Last accessed April 24, 2008).

Airaksinen O, Brox JI, Cedraschi C, et al. European guidelines for the management of chronic nonspecific low back pain. Eur Spine J 2006;15(Suppl 2):S192-S300.

An H, Boden SD, Kang J, et al. Emerging Techniques for Treatment of Degenerative Lumbar Disc Disease. Spine 2003;28(15S):S24-S25.

Andersen KH, Mosdal C, Vaernet K. Percutaneous Radiofrequency Facet Denervation in Low-Back and Extremity Pain. Acta Neurochir (Wein) 1987;87:48-51.

Anderson G, Boden S, Bridwell K, et al. Breaking down the barriers to restore public confidence: disclosure. Spine 2002;27:6-10.

Andersson GB, Mekhail NA, Block JE. Letter to the Editor RE: Cochrane Review, Gibson and Waddell. Spine 2006;31(12):1402-1403.

Andersson GB, Mekhail NA, Block JE. Letter to the Editor RE: A Randomized, Double-Blind, Controlled Trial: Intradiscal Electrothermal Therapy Versus Placebo for the Treatment of Chronic Discogenic Low Back Pain by Freeman et al. (Spine 2005;30:2369-77). Spine 2006;31(14):1637-1638.

Andersson GB, Mekhail NA, Block JE. Treatment of Intractable Discogenic Low Back Pain. A Systematic Review of Spinal Fusion and Intradiscal Electrothermal Therapy (IDET). Pain Physician 2006;9(3);237-248.

Andersson GB, Block JE. Letter to the Editor RE: Urrutia G, Kovacs F, Nishishinya MB, et al. Percutaneous thermocoagulation intradiscal techniques for discogenic low back pain. Spine 2007;32:1146-54. Spine 2007;32(25):2927-2929.

Andersson GB, Bridwell KH, Danielsson A, et al. Evidence-Based Medicine Summary Statement. Spine 2007;32(195S):S64-S65.

Aoki Y, Ohtori S, Takahashi K, et al. Innervation of the Lumbar Intervertebral Disc by Nerve Growth Factor-Dependent Neurons Related to Inflammatory Pain. Spine 2004;29(10):1077-81.

Appleby D, Andersson, G, Totta M. Meta-Analysis of the efficacy and Safety of Intradiscal Electrothermal Therapy (IDET). Pain Medicine 2006;7(4):308-316.

Arnau J, Pellise F, Vallano A, Prat N. Editorial Comment: European guidelines for low back pain – A necessary step forward and an opportunity not to be missed. Eur Spine J 2006;15(Suppl. 2):S131-S133.

Arnau J, Vallano A, Lopez A, et al. A critical review of guidelines for low back pain treatment. Eur Spine J 2006;15:543-553.

Bhagia S, Slipman C, Nirschl M, et al. Side Effects and Complications After Percutaneous Disc Decompression Using Coblation Technology. Am J Phys Med Rehabil 2006;85(1):6-13.

Barendse G, van den Berg S, Kessels A, et al. Randomized Controlled Trial of Percutaneous Intradiscal Radiofrequency Thermocoagulation for Chronic Discogenic Back Pain. Spine 2001;26(3):287-292.

Biyani A, Andersson G, Chaudhary H, An H. Intradiscal Electrothermal Therapy. Spine 2003;28(15S):S8-S14.

Bogduk N, Tynan W, Wilson AS. The nerve supply to the human lumbar intervertebral discs. J Anat 1981;132(1):39-56.

Bogduk N. The Innervation of the Lumbar Spine. Spine 1983;8(3):286-93.

Bogduk N. The Lumbar Disc and Low Back Pain. Neurosurgery Clinics of North America 1991;2(4):791-806.

Bogduk N, Karasek M. Two-year follow-up of a controlled trial of intradiscal electrothermal annuloplasty for chronic low back pain resulting from internal disc disruption. The Spine Journal 2002;2:343-350.

Bogduk N, Lau P, Govind J, Karasek M. Intradiscal electrothermal therapy. Techniques in Regional Anesthesia & Pain Management 2005;9:25-34.

Bombardier C. *Spine* Focus Issue Introduction, Outcome Assessments in the Evaluation of Treatment of Spinal Disorders. Spine 2000a;25(24):3097-3099.

Bombardier C. Outcome Assessments in the Evaluation of Treatment of Spinal Disorders, Summary and General Recommendations. Spine 2000b;25(24):3100-3103.

Bombardier C, Hayden J, Beaton D. Minimal Clinically Important Difference. Low Back Pain: Outcome Measures. J Rheumatol 2001;28:431-8.

Bombardier C. Outcome Assessments in the Evaluation of Treatment of Spinal Disorders. Spine 2000;25(24):3100-3103.

Bono C, Iki K, Jalota A, et al. Temperatures Within the Lumbar Disc and Endplates During Intradiscal Electrothermal Therapy: Formulation of a Predictive Temperature Map in Relation to Distance From the Catheter. Spine 2004;29(10):1124-1131.

Borggrefe M, Hindricks G, Haverkamp W, Breithardt G. Catheter Ablation Using Radiofrequency Energy. Clin Cardiol 1990;13:127-131.

Boswell M, Wolfe J. Intrathecal Cefazolin-Induced Seizures Following Attempted Discography. Pain Physician 2004;7:103-106.

Boswell M, Trescot A, Datta S, et al. Interventional Techniques: Evidence-based practice Guidelines in the Management of Chronic Spinal Pain. Pain Physician 2007;10:7-111.

Brisby H. Pathology and Possible Mechanisms of Nervous System Response to Disc Degeneration. J of Bone and Joint Surgery 2006;88A(Suppl 2):68-71.

Brox J, Sorensen R, Friis A, et al. Randomized Clinical Trial of Lumbar Instrumented Fusion and Cognitive Intervention and Exercises in Patients with Chronic Low Back Pain and Disc Degeneration. Spine 2003;28(17):1913-1921.

Bryce D, Nelson J, Glurich I, Berg R. Intradiscal Electrothermal Annuloplasty Therapy: A Case Series Study Leading to New Considerations. WMJ 2005 Aug;104(6):39-46.

Buenaventura R, Shah R, Patel V, t al. Systematic Review of Discography as a Diagnostic Test for Spinal Pain: An Update. Paine Physician 2007;10:147-164.

Burke JG, Watson RWG, McCormack D, et al. Intervertebral discs which cause low back pain secrete high levels of proinflammatory mediators. The J of Bone and Joint Surgery 2002;84-B(2):196-201.

Burton CV. Percutaneous Radiofrequency Facet Denervation. Appl Neurophysiol 1976/77;39:80-86.

Can thermal therapy relieve discogenic pain? The Backletter 1999;14(1):1, 9-10.

Carey T, Boden S. A Critical Guide to Case Series Reports. Spine 2003;28(15):1631-1634.

Carey T. Point of View. Spine 2005;30(21):2378.

Carey T, Mielenz T. Measuring Outcomes in Back Care. Spine 2007;32(11S):S9-S14.

Carey T, Garrett JM, Jackman AM. Beyond the Good Prognosis Examination of an Inception Cohort of Patients With Chronic Low Back Pain. Spine 2000;25(1):115-120.

Carragee E, Tanner C, Yand B, et al. False-Positive Findings on Lumbar Discography Reliability of Subjective Concordance Assessment During Provocative Disc Injection. Spine 1999;24(23):2542-2547.

Carragee E. Is Lumbar Discography a Determinate of Discogenic Low Back Pain: Provocative Discography Reconsidered. Current Review of Pain 2000;4:301-308.

Carragee E, Paragioudakis S, Khurana S. Lumbar High-Intensity Zone and Discography in Subjects Without Low Back Problems. Spine 2000;25(23):2987-2992.

Carragee E, Tanner C, Khurana S, et al. The Rates of False-Positive Lumbar Discography in Select Patients Without Low Back Symptoms. Spine 2000;25(1):1373-1381.

Carragee E, Chen Y, Tanner C, et al. Provocative Discography in Patients After Limited Lumbar Discectomy A controlled, Randomized Study of Pain Response in Symptomatic and Asymptomatic Subjects. Spine 2000;25(23):3065-3071.

Carragee E. Commentary. The Spine Journal 2007;7:88-93.

Cavanaugh J, Kallakuri S, Ozaktay C. Innervation of the Rabbit Lumbar Intervertebral Disc and Posterior Longitudinal Ligament. Spine 1995;20(19):2080-2085.

Chen Y, Derby R, Lee S. Percutaneous disc decompression in the management of chronic low back pain. Orthopedic Clinics of North America 2004;35:17-23.

Chou L, Lew H, Coelho P, Slipman C. Intradiscal Electrothermal Annuloplasty. Am J Phys Med Rehabil 2005;84(7):538-549.

Chou R, Qaseem A, Snow V, et al. Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline for the American College of Physicians and the American Pain Society. Ann Inter Med 2007;147:478-491.

Cohen S, Larkin T, Polly D. A Giant Herniated Disc Following Intradiscal Electrothermal Therapy. J of Spinal Disorders & Techniques 2002;15(6):537-541.

Cohen S, Larkin T, Abdi S, et al. Risk Factors for Failure and Complications of Intradiscal Electrothermal Therapy: A Pilot Study. Spine 2003;28(11):1142-1147.

Cohen S, Larkin T. Sedation With Ketamine During Intradiscal Electrothermal Therapy. Spine 2004;29(14):1590-1592.

Cohen S, Larkin T, Barna S, et al. Lumbar Discography: A Comprehensive Review of Outcome Studies, Diagnostic Accuracy, and Principles. Regional Anesthesia and Pain Medicine 2005;30(2):163-183.

Cohen S, Williams S, Kurihara C, et al. Nucleoplasty With or Without Intradiscal Electrothermal Therapy (IDET) as a Treatment for Lumbar Herniated Disc. J Spinal Disord Tech 2005;18(S1):S119-S124.

Cohen S, Shockey S, Carragee E. The Efficacy of Repeat Intradiscal Electrothermal Therapy. Anesth Analg 2007;105:495-8.

Coopes M, Marani E, Thomeer R, Groen G. Innervation of “Painful” Lumbar Discs. Spine 1997;22(20):2342-2350.

Corica A, Marianetti A, Anchelerguez R, et al. Transurethral Radio Frequency Thermotherapy for Symptomatic Benign Prostatic Hyperplasia. Eur Urol 1993;23:312-317.

Davis T, Delamarter R, Sra P, Goldstein T. The IDET Procedure for Chronic Discogenic Low Back Pain. Spine 2004;29(7):752-756.

DeAngelis C. Reply to Henschke and Yankelevitz letter: Unreported

Deen HG, Fenton D, Lamer T. Minimally Invasive Procedures for Disorders of the Lumbar Spine. Mayo Clinic Proceedings 2003 Oct;78(10):1249- 1256.

Derby R, Eek B, Chen Y, et al. Intradiscal Electrothermal Annuloplasty (IDET): A Novel Approach for Treating Chronic Discogenic Back Pain. Neuromodulation 2000;3(2):82-88.

Derby R, Lee S, Seo K, et al, Efficacy of IDET for Relief of Leg Pain Associated with Discogenic Low Back Pain. Paine Practice 2004;4(4):281-285.

Derby R, Kin BJ. Effect of Intradiscal Electrothermal Treatment with a Short Heating Catheter and Fibrin on Discogenic Low Back Pain. Am J of Phys Med & Rehabil 2005;84(7):560-561.

Derby R, Seo K, Kazala K, et al. A factor analysis of lumbar intradiscal electrothermal annuloplasty outcomes. The Spine Journal 2005;5:256-262.

Derby R, Baker R, Lee CH, Anderson P. Evidence-informed management of chronic low back pain with intradiscal electrothermal therapy. The Spine Journal 2008;8:80-95.

Deyo R, Battie M, Beurskens AJ, et al. Outcome Measures for Low Back Pain Research. Spine 1998;23(1):2003-2013.

Deyo R. Editorial Treatments for Back Pain: Can We Get Past Trivial Effects? Ann of Internal Med 2004 Dec;141(12):957-958.

Deyo R. Gaps, Tensions, and Conflicts in the FDA Approval Process: Implications for Clinical Practice. J Am Board Fam Pract 2004 March-April;17(2):142-149.

DiFabio R. Efficacy of Comprehensive Rehabilitation Programs and Back School for Patients With Low Back Pain: A Meta-analysis. Physical Therapy 1995 Oct;75(10):865-878.

Djurasovic M, Glassman S, Dimar J, Johnson J. Vertebral Osteonecrosis Associated With the Use of Intradiscal Electrothermal Therapy. Spine 2002;27(13):E325-E328.

Donelson R. Letter to the Editor RE: Bouter L, Pennick V, Bombardier C. Cochrane Back Review Group. Spine 2003;28:1215-1218.

Eckel T, Ortiz O. Intradiscal Electrothermal Therapy in the Treatment of Discogenic Low Back Pain. Techniques in Vas and Interv Radiology 2002 Dec;5(4):217-222.

ECRI Target Database. Intradiscal electrothermal annuloplasty for discogenic pain. June 2007. Link to web page: G:\Orthopedics\Thermal Intradiscal Therapy\Thermal intradiscal articles\ECRI Target report on IDET.htm (Last accessed April 24, 2008).

Endres S, Fiedler G, Larson K. Effectiveness of Intradiscal Electrothermal Therapy in Increasing Function and Reducing Chronic Low Back Pain in Selected Patients. WMJ 2002;101:31-4.

Endres S. Letter to the Editor RE: More on IDET. WMJ 2002;101(8):4-5.

Ercelen O, Bulutcu E, Oktenoglu T, et al. Radiofrequency Lesioning Using Two Different Time Modalities for the Treatment of Lumbar Discogenic Pain: A Randomized Trial. Spine 2003;28(17):1922-1927.

Fanuele J, Birkmeyer N, Abdu W, et al. The Impact of Spinal Problems on the Health Status of Patients Have We Underestimated the Effect? Spine 2000;25(12):1509-1514.

Finch P. Radiofrequency Denervation of the Annulus Fibrosus: A Rationale. Tech in Reg Anes and pain Management 2004;8(1):41-45.

Finch P, Price L, Drummond P. Radiofrequency Heating of Painful Annular Disruptions one-Year Outcomes. J Spinal Disord Tech 2005;18:6-13.

Fiume D, Sherkat S, Callovini GM, et al. Treatment of the Failed Back Surgery Syndrome Due to Lumbo-Sacral Epidural Fibrosis. Acta Neurochir 1995;Suppl 64:116-118.

Freedman B, Cohen S, Kuklo T, et al. Intradiscal electrothermal therapy (IDET) for chronic low back pain in active-duty soldiers: 2-year follow-up. The Spine Journal 3003;3:502-509.

Freeman B, Walters R, Moore R, Fraser R. Does Intradiscal Electrothermal Therapy Denervate and Repair Experimentally Induced Posterolateral Annular Tears in an Animal Model? Spine 2003;28(23):2602-2608.

Freeman B, Fraser R, Cain C, et al. A Randomized, Double-Blind, Controlled Trial Intradiscal Electrothermal Therapy Versus Placebo for the Treatment of Chronic Discogenic Low Back Pain. Spine 2005;30(21):2369-2377.

Freeman B. IDET: a critical appraisal of the evidence. Eur Spine J 2006;15(Suppl 3):S448-S457.

Freeman B, Mehdian R. Intradiscal Electrothermal Therapy, Percutaneous Discectomy, and Nucleoplasty: What Is the Current Evidence? Current Pain and Headache Reports 2008;12:14-21.

Freemont AJ, Peacock TE, Goupille P, et al. Nerve ingrowth into diseased intervertebral disc in chronic back pain. Lancet 1997;350:178-81.

Fukui S. Changes on MRI in lumbar disc protrusions in two patients after intradiscal electrothermal therapy. J Anesth 2006;20:132-134.

Gerszten P, Welch W, McGrath P, Willis S. A Prospective Outcomes Study of Patients Undergoing Intradiscal Electrothermy (IDET) for Chronic Low Back Pain. Pain Physician 2002;5(4):360-364.

Gibson J, Waddell G. Letter to the Editor Response to Andersson G, Mekhail N, Block JE. Spine 2006;31(12):1402-1403.

Guzman J, Esmail R, Karjalainen K, et al. Multidisciplinary rehabilitation for chronic low back pain: systematic review. BMJ 2001;322:1511-1511.

Hacker R. Comparison of Interbody Fusion Approaches for Disabling Low Back Pain. Spine 1997;22(6):660-665.

Hagg O, Fritzell P, Nordwall A. The clinical importance of changes in outcome scores after treatment for chronic low back pain. Eur Spine J 2003;12:12-20.

Haldeman S. Low Back Pain. Neurological Clinics of North Am 1999;17(1):1-15.

Haldeman S, Dagenais S. A supermarket approach to the evidence-informed management of chronic low back pain. The Spine J 2008a;8:1-7.

Haldeman S, Dagenais S. Editorial: What have we learned about the evidence-informed management of chronic low back pain? The Spine J 2008b;8:266-277.

Heary R. Intradiscal Electrothermal Annuloplasty: The IDET Procedure. J of Spinal Disorders 2001;14(4):353-360.

Henschke C, Yandelevitz D. Letter. Unreported Financial Disclosures. JAMA 2008;299(15):1770.

Holt A, Shaw N, Shetty A, Greenough C. The Reliability of the Low Back Outcome Score for Back Pain. Spine 2002;27(2):206-210.

Hsia A, Isaac K, Katz J. Cauda equine syndrome from intradiscal electrothermal therapy. Neurology 2000;55(2):320.

Huang R, Sandhu H. The current status of lumbar total disc replacement. Orthop Clin N Am 2004;35:3-42.

Hurri H, Karppinen J. Topical Review Discogenic pain. Pain 2004;112:225-228.

Institute for Clinical Systems Improvement (ICIS). Technology Assessment: Intradiscal Electrothermal Therapy (IDET) for Low Back Pain. April 2002. Link to web page: http://www.aetmis.gouv.qc.ca/site/250.403.0.0.1.0.phtml (Last accessed April 24, 2008).

ISIS Practice Guidelines, Spinal Diagnostic & Treatment Procedures. Edited by N. Bogduk. Methods p. XIX, Part One: Established Procedures, Therapeutic, Intradiscal Electrothermal Therapy. p 219-236.

Jarvik J, Deyo R. Diagnostic Evaluation of Low Back Pin with Emphasis on Imaging. Ann Intern Med 2002;137:586-597.

Jones G, Johnson R, Wiles N, et al. Predicting persistent disabling low back pain in general practice: a prospective cohort study. British J of Gen Pract 2006;56:334-341.

Kapural L, Mekhail N, Korunda Z, Basali A. Intradiscal Thermal Annuloplasty for the Treatment of Lumbar Discogenic Pain in Patients with Multilevel Degenerative Disc Disease. Anesth Analg 2004;99:472-6.

Kapural L, Hayek S, Malak O, et al. Intradiscal Thermal Annuloplasty Versus Intradiscal Radiofrequency Ablation for the Treatment of Discogenic Pain: A Prospective Matched Control Trial. Pain Medicine 2005;6(6):425-431.

Kapural L, Mekhail N. Letter to the Editor RE: A Randomized, Double-Blind, Controlled Trial: Intradiscal Electrothermal Therapy Versus Placebo for the Treatment of Chronic Discogenic Low Back Pain by Freeman et al. Spine 2005;30:2369 -77. Spine 2006;31(14):1636-1638.

Kapural L, Mekhail N. Novel Intradiscal Biacuplasty (IDB) for the Treatment of Lumbar Discogenic Pain. Pain Practice 2007;7(2):130-134.

Kapural L, Cata J. Complications of percutaneous techniques used in the diagnosis and treatment of discogenic lower back pain. Tech in Reg Anest & Pain Management 2007;11:157-163.

Kapural L, Ng A, Dalton J, et al. Intervertebral Biacuplasty for the Treatment of Lumbar Discogenic Pain: Results of a Six -Month Follow-up. Pain Medicine 2008;9(1):60-67.

Kapural L, Mekhail N, Hicks D, et al. Histological Changes and Temperature Distribution Studies of a Novel Bipolar Radiofrequency Heating System in Degenerated and Nondegenerated Human Cadaver Lumbar Discs. Pain Medicine 2008;9(1):68-75.

Karasek M, Bogduk N. Twelve-Month Follow-up of a Controlled Trial of Intradiscal Thermal Anuloplasty for Back Pain Due to Internal Disc Disruption. Spine 2000;25(20):2601-2607.

Kennedy M. IDET: A new approach to treating lower back pain. WMJ 1999;98(6):18-20.

Kim P, Branch C. The Lumbar Degenerative Disc: Confusion, Mechanics, Management. Clinical Neurosurgery 2006;53:18-25.

Kleinstueck F, Diederich C, Nau W, et al. Acute Biomechanical and Histological Effects of Intradiscal Electrothermal Therapy on Human Lumbar Discs. Spine 2001;26(20):2198-2207.

Kleinstueck F, Diederich C, Nau W. Temperature and Thermal Dose Distributions During Intradiscal Electrothermal Therapy in the Cadaveric Lumbar Spine. Spine 2003;28(15):1700-1709.

Koshi E, Short C. Placebo Theory and Its Implications for Research and Clinical Practice: A Review of the Recent Literature. Pain Practice 2007;7(1):4-20.

Lee J, Lutz G, Campbell D, et al. Stability of the Lumbar Spine After Intradiscal Electrothermal Therapy. Arch Phys Med Rehabil 2001;82:120-2

Lee M, Cooper G, Lutz G, et al. Intradiscal Electrothermal Therapy (IDET) for Treatment of Chronic Lumbar Discogenic Pain: A Minimum 2-Year Clinical Outcome Study. Pain Physician 2003;6:443-448.

Lee M, Cooper G, Lutz G, Doty S. Histological Characterization of Coblation Nucleoplasty Performed on Sheep intervertebral Discs. Pain Physician 2003;6:439-442.

Linton S. A Review of Psychological Risk Factors in Back and Neck Pain. Spine 2000;25(9):1148-1156.

Lorig K, Laurent D, Deyo R, et al. Can a Back Pain E-mail Discussion Group Improve Health Status and Lower Health Care Costs? Arch Intern Med 2002;162:792-796.

Lotz J, Diederich C. Point of View. Spine 2004;29(10):1130-31.

Lutz C, Lutz G, Cooke P. Treatment of Chronic Lumbar Diskogenic Pain With Intradiskal Electrothermal Therapy: A Prospective Outcome Study. Arch Phys Med Rehabil 2003;84:23-8.

Malik K. Treatment of multilevel degenerative disc disease with intradiscal electrothermal therapy. Anaesth Intensive Care 2007;35:289-293.

Malik K, Joseph N. Intervertebral Disc A Source of pain? Low Back Pain: Problems and Future Directions Case reports. MEJ Anesth 2009;19(3):683-92.

Manchikanti L. Medicare in Interventional Pain Management: A Critical Analysis. Pain Physician 2006;9:171-197.

Manek NJ, MacGregor AJ. Epidemiology of back disorders: prevalence, risk factors, and prognosis. Curr Opin Rheumatol 2005;17:134-140.

Marketos S, Skiadis P. Hippocrates: The Father of Spine Surgery. Spine 1999;24(13):1381-95.

Martin B, Deyo R, Mirza S, et al. Expenditures and Health Status Among Adults With Back and Neck Problems. JAMA 2008;299(6):656-664.

Masala S, Massari F, Fabiano S, et al. Nucleoplasty in the Treatment of Lumbar Diskogenic Back Pain: One Year Follow -Up. Cardiovasc Intervent Radiol 2007;30:426-432.

Maurer P, Squillante D. Is Intradiscal Electrothermal Annuloplasty (IDET) effective treatment fro discogenic low back pain? A prospective cohort outcome study identifying successful patient selection criteria. Proceedings of NASS 16th Annual Meeting./The Spine Journal 2002;2:37S.

Maurer P, Block JE, Squillante D. Intradiscal Electrothermal Therapy (IDET) Provides Effective Symptom Relief in Patients With Discogenic Low Back Pain. J Spinal Disord Tech 2008;21:55-62.

Mekhail N, Kapural L. Intradiscal Thermal Annuloplasty for Discogenic Pain: An Outcome Study. Pain Practice 2004;4(2):84-90.

Mirzai H, Tekin I, Yaman O, Bursali A. The results of nucleoplasty in patients with lumbar herniated disc: a prospective clinical study of 52 consecutive patients. The Spine Journal 2007;7:88-93.

Munter F, Wasserman B, Wu HM, Yousem D. Serial MR Imaging of Annular Tears in Lumbar Intervertebral Disks. Am J Neuroradiol 2002;23:1105-1109.

Murphy A, van Teijlingen E, Gobbi M. Inconsistent Grading of Evidence Across Countries: A Review of Low Back Pain Guidelines. J Manipulative Physiol Ther 2006;29:576-581.e2.

Nachemson A. Low back pain in the year 2000 – “back” to the future. Bulletin Hospital for Joint Diseases, NY, NY 1996a;55(3):119-21.

Nachemson A. Work related low back pain treatment outcomes: the experience in Gothenburg, Sweden. Bulletin Hospital for Joint Diseases, NY, NY 1996b;55(4):203.

Nachemson A, Zdeblick A, O'Brien J. Controversy Lumbar Disc Disease With Discogenic Pain. Spine 1996;21(15):1835-1838.

Nachemson A. Editorial: Our challenge for the next millennium. J Orthop Sci 1998;3:191-193.

Nachemson A. Back Pain: Delimiting the Problem in the Next Millennium. International J of Law and Psychiatry 1999;22:5-6.

Nachemson A. Newest Knowledge of Low Back Pain, A Critical Look. Clinical Orthop and Related Research 1992;279:8-20.

Narvani AA, Tsiridis E, Ishaque MA, Wilson LF. "Pig Tail" Technique In Intradiscal Electrothermal Therapy. J of Spinal Disorders & Techniques 2003a;16(3):280-284.

Narvani AA, Tsiridis E, Wilson LF. High-Intensity Zone, Intradiscal Electrothermal Therapy, and Magnetic Resonance Imaging. J of Spinal Disorders & Techniques 2003b;16(2):130-136.

National Board of Health, Danish Centre for Evaluation and Health Technology Assessment, Health Technology Alert. Intradiscal electrothermal therapy (IDET) for low back pain. December 2003;2(7):1-4. http://www.sst.dk/publ/Publ2004/Tidlig_varsling_07_uk/index.html (Last accessed 4/23/2008).

National Institute for Health and Clinical Excellence Guidance; Percutaneous disc compression using coblation for lower back pain. May 2006. http://www.nice.org.uk/guidance/index.jsp?action=byID&r=true&o=11147 (Last accessed 4/17/2008).

National Institute for Health and Clinical Excellence Guidance; Percutaneous intradiscal electrothermal therapy for lower back pain. August 2004. http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11055 (Last accessed 4/17/2008).

National Institute for Health and Clinical Excellence Guidance; Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. August 2004. http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11115 (Last accessed 4/17/2008).

Nerubay J, Caspi I, Levinkoph M, et al. Percutaneous Laser Nucleolysis of the Intervertebral Lumbar Disc. Clinical Orthopaedics and Related Research 1997;337:42-44.

Niemisto L, Kalso E, Malmivaara A, et al. Radiofrequency Denervation for Neck and Back Pain: A Systematic Review Within the Framework of the Cochrane Collaboration Back Review Group. Spine 2003;28(16):1877-1888.

Nunley P, Jawahar A, Brandao S, Wilkinson K. Intradiscal Electrothermal Therapy (IDET) for Low Back Pain in Worker's Compensation Patients, Can It Provide a Potential Answer? Long-term Results. J Spinal Disord Tech 2008;21:11-18.

Oh WS, Shim JC. A Randomized Controlled Trial of Radiofrequency Denervation of the Ramus Communicans Nerve for Chronic Discogenic Low Back Pain. Clin J pain 2004;20(1):55-60.

O'Neill C, Kurgansky M, Derby R, Ryan D. Disc Stimulation and Patterns of Referred Pain. Spine 2002;27(24):2776-2781.

Orr RD, Thomas SA. Intradural Migration of Broken IDET Catheter Causing a Radiculopathy. J Spinal Disord Tech 2005;18(2):185-187.

Ostelo R, Deyo R, Stratford P, et al. Interpreting Change Scores and Functional Status in Low Back Pain. Spine 2008;33(1):90-94.

Park SY, Moon SH, Park MS, et al. Intradiscal Electrothermal Treatment for Chronic Lower Back Pain Patients with Internal Disc Disruption. Yonsei Medical Journal 2005;46(4):539-545.

Pauza K, Howell S, Dreyfuss P, et al. A randomized, placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. The Spine Journal 2004;4:27-35.

Peng B, Wu W, Hou S, et al. The pathogenesis of discogenic low back pain. J of Bone and Joint Surgery 2005;87(1):62-67.

Peng B, Hou S, Wu W, et al. The pathogenesis and clinical significance of a high-intensity zone (HIZ) of lumbar intervertebral disc on MR imaging in the patient with discogenic low back pain. Eur Spine J 2006;15:583-587.

Peng B, Hou J, Hou S, et al. Possible Pathogenesis of Painful Intervertebral Disc Degeneration. Spine 2006;31(5):560-566.

Petersohn J, Conquergood L, Leung M. Acute Histologic Effects and Thermal Distribution Profile of Disc Biacuplasty Using a Novel Water-Cooled Bipolar Electrode System in a in vivo Porcine Model. Pain Medicine 2007.

Pincus T, Burton AK, Vogel S, Field A. A Systematic Review of Psychological Factors as Predictors of Chronicity/Disability in Prospective Cohorts of Low Back Pain. Spine 2002;27(5):E109-E120.

Pollintine P, Findlay G, Adams M. Intradiscal Electrothermal Therapy Can Alter Compressive Stress Distributions Inside Degenerated Intervertebral Discs. Spine 2005;30(6):E134-E139.

Pomerantz S, Hirsch J. Intradiscal Therapies for Discogenic Pain. Seminars in Musculoskeletal Radiology 2006;10(2):125-135.

Raspe H, Matthis C, Croft P, et al. Variation in Back Pain Between Countries, The Example of Britain and Germany. Spine 2004;29(9):1017-1021.

Ray CD. Threaded Fusion Cages for Lumbar Interbody Fusions: An Economic Comparison with 360° Fusions. Spine 1997;22(6):681-685.

Resnick D. Evidence-Based Spine Surgery. Spine 2007;32(11S):S15-S19.

Rhyne, III, AL, Smith SE, Wood KE, Darden BV. Outcome of Unoperated Discogram-Positive Low Back Pain. Spine 1995;20(18):1997-2001.

Rozen D, Grass GW. Intradiscal Electrothermal Coagulation and Percutaneous Neuromodulation Therapy in the Treatment of Discogenic Low Back Pain. Pain Practice 2005;5(3):228-243.

Rosen S, Falco F. Radiofrequency Stimulation of Intervertebral Discs. Pain Physician 2003;6:435-438.

Saal JA, Saal JS. Intradiscal Electrothermal Treatment for Chronic Discogenic Low Back Pain, A Prospective Outcome Study With Minimum 1-Year Follow-up. Spine 2000a;25(20):2622-2627.

Saal JA, Saal JS. Management of Chronic Discogenic Low Back Pain With a Thermal Intradiscal Catheter. Spine 2000b;25(3):382-388.

Saal JA, Saal JS. Intradiscal Electrothermal Treatment for Chronic Discogenic Low Back Pain, A Prospective Outcome Study With Minimum 2-Year Follow-up. Spine 2002a;27(9):966-974.

Saal JA, Saal JS. Intradiscal Electrothermal Therapy for the Treatment of Chronic Discogenic Low Back Pain. Clinics in Sports Med 2002;21(1):167-187.

Salovey P, Seiber WJ, Smith AF, et al. Reporting chronic pain episodes on health surveys. National Center for Health Statistics. Vital Health Stat 6(6). 1992. http://www.cdc.gov/nchs/data/series/sr_06/sr06_006.pdf (Last accessed on 4/17/2008).

Samartzis D, Shen FH, Perez-Cruet MJ, Anderson DG. Minimally Invasive Spine Surgery: A Historical Perspective. Orthopedic Clinics of N Am 2007;38:305-326.

Sanders SH, Harden RN, Vicente PJ. Evidence-Based Clinical Practice Guidelines for Interdisciplinary Rehabilitation of Chronic Nonmalignant Pain Syndrome Patients. Paine Practice 2005;5(4):303-315.

Schmolke S, Kirsch L, Gosse F, et al. Risk Evaluation of Thermal Injury to the Cervical Spine during Intradiscal Laser Application in Vitro. Photomedicine and Laser Surgery 2004;22(5):426-430.

Schneiderman G, Flannigan B, Kingston S, et al. Magnetic Resonance Imaging in the Diagnosis of Disc Degeneration: Correlation with Discography. Spine 1987;12(3):276-81.

Schoene M. A Tribute to Alf Nachemson: The Spine Interview. The Backletter 2007;22(1):13-21.

Scholl BM, Theiss SM, Lopez-Ben R, Kraft M. Vertebral Osteonecrosis Related to Intradiscal Electrothermal Therapy, A Case Report. Spine 2003;28(9):E161-E164.

Schwarzer AC, Aprill CN, Derby R, et al. The Prevalence and Clinical Features of Internal Disc Disruption in Patients With Chronic Low Back Pain. Spine 1999;20(17):1878-1883.

Shah RV, Lutz GE, Lee J, et al. Intradiskal Electrothermal Therapy: A Preliminary Histologic Study. Arch Phys Med Rehabil 2001;82:1230-1237.

Shah RV, Facz GB. Long-Term Relief of Posttraumatic Headache by Sphenopalatine Ganglion Pulsed Radiofrequency Lesioning: A Case Report. Arch Phys Med Rehabil 2004;85: 1013-1016.

Shah RV, Everett CR, McKenzie-Brown AM, Sehgal N. Discography as a Diagnostic Test for Spinal Pain: A Systematic and Narrative Review. Pain Physician 2005;81:187-209.

Shah RV, Albert TJ, Bruegel-Sanchez V, et al. Industry Support and Correlation to Study Outcome for Papers Published in Spine. Spine 2005;30(9):1099-1104.

Sharp criticism of intradiscal thermal therapy research. The Backletter 2000;15(6):61-64.

Sharps LS, Isaac Z. Percutaneous Disc Decompression Using Nucleoplasty. Pain Physician 2002;5(2):121-126.

Singh V. Intradiscal Electrothermal Therapy: A Preliminary Report. Pain Physician 2000;3(4):367-373.

Singh V, Piryani C, Liao K, Nieschulz S. Percutaneous Disc Decompression Using Coblation (Nucleoplasty™) in the Treatment of Chronic Discogenic Pain. Pain Physician 2002;5(3):250-259.

Singh V, Piryani C, Liao K. Evaluation of Percutaneous Disc Decompression Using Coblation in Chronic Back Pain With or Without Leg Pain. Pain Physician 2003;6:273-280.

Singh V, Piryani C, Liao K. Role of Percutaneous Disc Decompression Using Coblation in Managing Chronic Discogenic Low Back Pain: A Prospective, Observational Study. Pain Physician 2004;7:419-425.

Singh K, Ledet E, Carl A. Intradiscal Therapy, A Review of Current Treatment Modalities. Spine 2005;30(17S):S20-S26.

Singh V, Derby R. Percutaneous Lumbar Disc Decompression. Pain Physician 2006;9:139-146.

Slipman CW, Patel RK, Zhang L, et al. Side of Symptomatic Annular Tear and Site of Low Back Pain. Spine 2001;26(8):E165-E169.

Slipman CW, Bhat AL, Gilschrist RV, Issac Z, et al. Preliminary results for axial low back pain treated with coblation: a comparison of patients with and without a central focal protrusion. European Spine Journal 2002;11:416-7.

Smith BM, Hurwitz EL, Solsberg D, et al. Interobserver Reliability of Detecting Lumbar Intervertebral Disc High-Intensity Zone on Magnetic Resonance Imaging and Association of High-Intensity Zone With Pain and Anular Disruption. Spine 1998;23(19):2074-2080.

Smith HP, McWhorter JM, Challa VR. Radiofrequency neurolysis in a clinical model. J Neurosurg 1981;55:246-253.

Spruit M, Jacobs WCH. Pain and function after intradiscal electrothermal treatment (IDET) for symptomatic lumbar disc degeneration. Eur Spine J 2002;11:589-593.

Stadnik TW, Lee RR, Coen HL, et al. Annular Tears and Disk Herniation: Prevalence and Contrast Enhancement on MR Images in the Absence of Low Back Pain or Sciatica. Radiology 1998;206:49-55.

Stewart WF, Ricci JA, Chee E, et al. Lost Productive Time and Cost Due to Common Pain Conditions in the US Workforce. JAMA 2003;209(18):2443-2454.

Tafazal SI, Sell PJ. Outcome scores in spinal surgery quantified: excellent, good, fair and poor in terms of patient-completed tools. Eur Spine J 2006;15:1653-1660.

Theodossiou T, Rapti GS, Hovhannisyan V, et al. Thermally Induced Irreversible Conformational Changes in Collagen Probed by Optical Second Harmonic Generation and Laser-induced Fluorescence. Lasers Med Sci 2002;17:34-41.

Thomas E, Silman AJ, Croft PR, et al. Predicting who develops chronic low back pain in primary care: a prospective study. BMJ 1999;318:1662-7.

Thompson K, Eckel T. Two-year results from the Intradiscal Electrothermal Therapy nationwide registry. Proceedings of NASS 16th Annual Meeting./The Spine Journal 2002;2:10S.

Thongtrangan I, Le H, Park J, Kim DH. Minimally invasive spinal surgery: a historical perspective. Neurosurg Focus 2004;16(1):1-10.

Tice J. California Technology Assessment Fourm. IDET – Intradiscal Electrothermal Therapy for Treatment of Back Pain. 2003. Link to web page: http://www.ctaf.org/content/general/detail/551 (Last accessed April 24, 2008).

Tiktopulo EI, Kajava AV. Denaturation of Type I Collagen Fibrils Is an Endothermic Process Accompanied by a Noticeable Change in the Partial Heat Capacity. Biochemistry 1988;37:8147-8152.

Troussier B, Lebas JF, Chirossel JP, et al. Percutaneous Intradiscal Radio-Frequency Thermaocoagulation, A Cadaveric Study. Spine 1995;20(15):1713-1718.

Tsou PM, Yeung CA, Yeung AT. Posterolateral transforaminal selective Endoscopic discectomy and thermal annuloplasty for chronic lumbar discogenic pain: a minimal access visualized intradiscal surgical procedure. The Spine J 2004;4:564-573.

Turner JA, Deyo RA, Loeser JD, et al. The Importance of Placebo Effects in Pain Treatment and Research. JAMA 1994;271(20):1600-1614.

Urrutia G, Kovacs F, Nishishinya MB, Olabe J. Percutaneous Thermocoagulation Intradiscal Techniques for Discogenic Low Back Pain. Spine 2007;32(10):1146-1154.

U.S. Preventive Services Task Force. Guide to clinical preventive services, 2nd ed. Baltimore: Williams & Wilkins, 1996: 699.

van Kleef M, Spaans F, Dingemans W, et al. Effects and side effects of percutaneous thermal lesion of the dorsal root ganglion in patients with cervical pain syndrome. Pain 1993;52:49-53.

von Korff M. Studying the Natural History of Back Pain. Spine 1994;19(18S):2041S-2046S.

Vanharanta H, Sachs BL, Guyer RD, et al. Pain Provocation and Disc Deterioration by Age, A CT/Discography Study in a Low-Back Pain Population. Spine 1989;14(4):420-3.

Ware Jr. JE. Editorial: Using Generic Measures of Functional Health and Well-Being to Increase Understanding of Disease Burden. Spine 2000a;25(12):1467.

Ware Jr. JE. SF-36 Health Survey Update. Spine 2000b;25(24):3130-3139.

Webster BS, Verma S, Pransky GS. Outcomes of Workers' Compensation Claimants With Low Back Pain Undergoing Intradiscal Electrothermal Therapy. Spine 2004;29(4):435-441.

Weiner DK, Kim YS, Bonino P, Wang T. Low Back Pain in Older Adults: Are We Utilizing Healthcare Resources Wisely? Pain Medicine 2006;7(2):143-150.

Weinstein J. Threats to Scientific Advancement in Clinical Practice. Spine 2007;32(11S):S58-S62.

Weinstein JN, Clay K, Morgan T. Informed Patient Choice: Patient-Centered Valuing of Surgical Risks and Benefits. Health Affairs 2007;26(3):726-730.

Welch WC, Gerszten PC, McGrath P. Intradiscal Electrothermy: Indications, Techniques, and Clinical Results. Clin Neurosurg 2001;48:219-25.

Welch WC, Gerszten PC. Alternative Strategies for lumbar discectomy: intradiscal electrothermy and nucleoplasty. Neoursurg Focus 2002;13(2):1-6.

Wetzel FT, McNally TA, Phillips FM. Intradiscal Electrothermal Therapy Used to Manage Chronic Discogenic Low Back Pain. Spine 2002;27(22):2621-2626.

Wetzel FT, McNally TA. New directions and interventions: Intradiscal electrothermal annuloplasty to treat chronic discogenic low back pain. Current Opinion in Orthopedics 2002;13(3):172-7.

Wetzel FT, McNally TA. Treatment of Chronic Discogenic Low Back Pain with Intradiskal Electrothermal Therapy. J Am Acad Orthop Surg 2003;11(1):6-11.

Wong W. Intradiscal Electrothermal Therapy (IDET). JBR-BTR 2003;86(5):297-9.

Yakovlev A, Tamimi MA, Liang H, Eristavi M. Outcomes of Percutaneous Disc Decompression Utilizing Nucleoplasty for the Treatment of Chronic Discogenic Pain. Pain Physician 2007;10:319-327.

Yeung AT. The Evolution of Percutaneous Spinal Endoscopy and Discectomy: State of the Art. The Mount Sinai J of Med 2000;67(4):327-332.

Yoshizawa H, O'Brien JP, Smith WT, Trumper M. The Neuropathology of Intervertebral Discs Removed for Low-Back Pain. J Pathol 1980;132(2):95-104.

Zhou Y, Abdi S. Diagnosis and Minimally Invasive Treatment of Lumbar Discogenic pain – A Review of the Literature. Clin J Pain 2006;22(5):468481.

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